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Supreme Court, U.S.
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No. 90-

IN THE

Supreme Court of the United States

OCTOBER TERM, 1990

ANNE ELISABETH KOLLER,

Petitioner,

v.

RICHARDSON-MERRELL, INC.,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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February 5, 1991

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QUESTIONS PRESENTED

1. Under Fed. R. Evid. 703, may federal courts exclude the testimony of concededly qualified expert witnesses solely on the finding that, given the weight of opposing expert testimony, the factual *conclusions* reached by the experts are incorrect and hence not "reasonable"?

2. Under the Federal Rules of Evidence, may the courts of appeals promulgate specialized, common-law evidence rules establishing "as a matter of law" the incorrectness, and hence inadmissibility, of particular conclusions about ultimate scientific facts?

3. Consistent with the Constitution, may the lower federal courts pursue efficiency in "mass tort" or other litigation by using a single case to pronounce binding conclusions of ultimate scientific fact on a key issue common to a category of cases — and thereafter bar all other litigants from trying that issue, even though they were not parties to, or represented in, the first case?

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OPINIONS BELOW

The *per curiam* order of the United States Court of Appeals for the District of Columbia Circuit granting summary affirmance is unreported and reprinted as Appendix A, at page A1.[1] The memorandum opinion of the United States District Court for the District of Columbia, granting judgment in favor of respondent and dismissing the complaint, is unreported and reprinted as Appendix B, at page A3.

JURISDICTION

The *per curiam* order of the Court of Appeals was announced on August 31, 1990. A timely petition for rehearing and suggestion for rehearing *en banc* was denied on November 7, 1990. See Appendix C, at page A11. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND CONSTITUTIONAL PROVISIONS INVOLVED

The Federal Rules of Evidence were enacted by Congress as a statute in 1975, Pub. L. No. 93-595, 88 Stat. 1926 (1975), 28 U.S.C. app. (1988). Rule 402 provides:

Rule 402. Relevant Evidence Generally Admissible; Irrelevant Evidence Inadmissible

> All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States,

[1] References to the appendices bound with this Petition are styled "A__". References to the four-volume Appellant's Appendix filed below in the Court of Appeals will be styled "C.A. App. __".

by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

Rule 104(a) of the Federal Rules of Evidence provides:

> **Rule 104. Preliminary Questions**
>
> **(a) Questions of admissibility generally.** Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges.

Rule 702 of the Federal Rules of Evidence provides:

> **Rule 702. Testimony by Experts**
>
> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Rule 703 of the Federal Rules of Evidence provides:

> **Rule 703. Bases of Opinion Testimony by Experts**
>
> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

The Fifth Amendment to the United States Constitution provides in relevant part:

> No person shall . . . be deprived of life, liberty, or property, without due process of law . . . .

The Seventh Amendment to the United States Constitution provides:

> In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law.

STATEMENT OF THE CASE

1. Summary

This case is one of many filed in the federal courts under diversity jurisdiction alleging birth defects from the anti-nausea drug Bendectin. It presents important and recurring issues, on which the circuits are in conflict, concerning the proper interpretation of the expert testimony rules enacted by Congress in the 1975 Federal Rules of Evidence, particularly Rule 703. This case also involves the constitutional issues raised by the current debate among the federal courts of appeals concerning attempts to reduce the burden of "mass tort" litigation by employing evidentiary rulings in *one* case to resolve disagreements among qualified experts, issuing a *general* pronouncement about scientific truth on a key issue, and then requiring that this pronouncement bind all future litigants even if they are thereby denied *their own* day in court on that key issue and its application to their case.

In the expert testimony rules that Congress enacted in order to greatly *expand* the range of expert opinion available to juries in federal trials, the D.C. Circuit below, as well as the First Circuit in an earlier case, have purported to find a device that supposedly *grants judges the power to try the entire case at the threshold level of admissibility*. Under Rule 703, these circuits have held, *all* of a party's expert opinion testimony on an issue may be excluded if the court decides that the ultimate *conclusion* of the experts is not "reasonable," because of the greater weight of the opposing experts' testimony. *See* pp. 11-15, *infra*. Several other circuits have, to a lesser extent, used Rule 703 to second-guess the persuasiveness of expert testimony. *See* pp. 24-25, *infra*. Solely under Rule 703, the court below required exclusion of the testimony of *all sixteen* experts who testified in support of the conclusion that Bendectin causes birth defects, including those who specifically stated that it caused petitioner's injuries. This tactic flouts Congress's clear language and intent in enacting Rule 703, under which the persuasiveness of an expert's conclusions is irrelevant — as several other circuits have held and as the Third Circuit has recently reiterated in another Bendectin case, expressly rejecting the contrary Bendectin decisions of the D.C. and First Circuits. (Part I, *infra*.) This Court should resolve the longstanding and important circuit conflict over the meaning of Rule 703, and in doing so overturn the extreme use of Rule 703 pioneered by the First and D.C. Circuits.

Moreover, in holding that certain conclusions reached by experts are incorrect and, therefore, "*as a matter of law*" are inadmissible in all future cases, the court below has engaged in exactly the type of traditional, circuit-by-circuit, common-law evidence rulemaking that the Federal Rules of Evidence — by requiring *uniform* rules for all classes of cases throughout the Nation — were passed to prevent. The Rules displace the power of lower federal courts to promulgate special evidentiary

rulings, as the court below has done with respect to Bendectin litigation. (Part II, *infra*). This Court should use this case to enforce Congress's basic policy choice and put an end to such impermissible aggrandizement of federal judicial power.

The ruling of the court below also presents grave constitutional issues that are increasingly confronting the lower federal courts as they work to resolve "mass tort" cases efficiently. The theory that federal judges can use the Federal Rules of Evidence to cut off jury trials on contested issues of fact, by nakedly weighing conflicting testimony in deciding which evidence to *admit*, violates the Seventh Amendment, which was passed in order to prevent such abuses by an autocratic Judiciary and thereby to help legitimate the Article III courts. For a court to attempt to put an end to "duplicative" litigation over similar issues by binding a litigant to a judgment about *ultimate scientific fact* reached in another case, to which he or she was not a party or privy, completely denies well-established rights to procedural due process. The separation-of-powers and federalism problems with Article III judges using individual cases to issue scientific edicts designed to end dispute over state-law issues are equally severe. (Part III, *infra*).

2. Factual Background

The issues presented on this petition concern not whether Bendectin causes birth defects in general, or whether it caused petitioner's particular birth defects, but rather how such scientific issues must be decided under the Federal Rules of Evidence and under the Constitution. For that reason it is not necessary to itemize the specific content of the scientific testimony in this case. An understanding of the questions presented for review does, however, require a sketch of the types of evidence that exist regarding Bendectin, and the differences in the methods of scientific investigation involved.

Bendectin was developed by respondent Richardson-Merrell, Inc. ("Merrell")[2] as an anti-nausea drug to be taken by pregnant women to combat morning sickness in early pregnancy. In 1956 the FDA permitted Bendectin to be placed on the market. At the time of initial marketing, neither Merrell nor the FDA had conducted any studies to determine the effect of the drug on the human fetus — a result of the prevailing scientific belief that the womb was a safehouse against environmental dangers. Although the embryos of amphibians, fish, and chicks had been shown "to be quite susceptible to unfavorable influences during development," these tests "were not generally accepted as purporting similar vulnerability for higher animals." J. Wilson, "Current Status of Teratology," in 1 *Handbook of Teratology* 47 (ed J. Wilson and F. Fraser 1977) (reprinted at C.A. App. Tab 27). Instead, "[i]t was widely assumed in biology and in medicine that the mammalian embryo developed within the virtually impervious shelter of the uterus and the maternal body where it was protected from extrinsic factors." *Ibid.*

Conventional scientific wisdom, of course, proved quite wrong several years later, with "the appearance of an epidemic of limb-reduction malformations" in babies whose mothers had taken the "presumably harmless sedative-hypnotic drug thalidomide," which made clear the vulnerability of human embryos "to certain environmental agents even though these have negligible or no toxic effects in postnatal individuals." *Id.* at 48. The thalidomide tragedy spurred the rapid development of the scientific field of "teratology" — the study of "teratogens," or substances that produce malformations in human fetuses. *Id.* at 48-49.

Teratology quickly became a major area of study in the pharmacology departments at virtually all universities, borrowing

[2] The company is now succeeded in interest by Merrell Dow Pharmaceuticals, Inc.

investigative techniques from the field of toxicology, which concerns itself with the effects of substances on living cells. As a widely prescribed drug, Bendectin fell under close scrutiny. Before the drug was removed from the market in 1983, doctors had filed thousands of reports with the FDA or Merrell noting deformed children born of Bendectin mothers. In light of such concerns, teratologists labored for over a decade, examining all feasible sources of information to determine whether Bendectin causes birth defects. Pharmacology data revealed that Bendectin's antihistaminic component (doxylamine succinate) crosses the placental barrier and therefore can cause defects to the fetus. As to *direct* evidence of causation, because experimentation on human fetuses is of course legally and ethically impermissible, teratologists relied on the standard substitute: controlled experimentation on animals. Breakthroughs in *in vitro* studies, involving microscopic examination of animal cells subjected to Bendectin while in the process of cell division, indicated that Bendectin could trigger abnormal cell development associated with birth defects. *In vivo* studies subjecting various animal species to dosages of Bendectin during fetal formation provided further evidence of teratogenicity.

As to *indirect*, circumstantial evidence of causation, researchers in the field of epidemiology began collecting human data through epidemiological studies comparing groups of women who had taken Bendectin during pregnancy with groups who had not, and reporting the incidence of birth defects in each group in an attempt to determine a correlation. The data from these studies usually indicated a substantially higher rate of birth defects among women taking Bendectin — although not as high a rate of defects as had occurred with thalidomide.

To be sure, in any one such epidemiological study taken alone, there was always the danger that the observed differences in the rate of deformities among Bendectin and non-Bendectin

mothers might be the result of chance, given the relatively small number of mothers in each study and difficulties in measuring exact levels of Bendectin usage and in controlling for other possible sources of birth defects. For this reason, scientists in the field of *epidemiology* have traditionally been unwilling to conclude that a *single* study constitutes evidence of causation unless it meets a strict test of "statistical significance" — i.e., when statistically they can be at least *95% confident* that an observed correlation is not due to chance. If the level of certainty falls even slightly short of this strict standard, the study will typically be reported as concluding that there is no indication of causation. *See DeLuca* v. *Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 945-49 (3d Cir. 1990). Thus epidemiologists might conduct a string of studies on Bendectin, *each one* indicating a *90% confidence* that Bendectin causes birth defects, and scientists in the field of epidemiology would report that there is *no "statistically significant" evidence of causation*.

Scientists in the field of *teratology*, however, routinely consider multiple sources of information in investigating whether substances cause birth defects. They assess epidemiological data in light of other data from direct experiments and thus place less reliance on the certainty demanded by "statistical significance" testing. By examining the data *as a whole*, including the actual observations made in *multiple* epidemiological studies, they reduce the danger of error from considering a single epidemiological study in isolation, so that continued use of "statistical significance" standards becomes arbitrary and unhelpful. *See, e.g., DeLuca, supra*, 911 F.2d at 947-49.

Based on these sources of data taken together, by the late 1970s a substantial number of eminent scientists in the field of teratology and related fields had reached the scientific conclusion that Bendectin is a potent teratogen capable of causing a wide variety of birth defects. As a result large numbers of lawsuits were filed alleging birth defects resulting from use of Bendectin.

To be sure, no consensus existed (or exists today) on the issue. Merrell found support among significant numbers of experts who questioned the strength of the various sources of evidence of causation. Merrell relied most heavily on specialists in the field of epidemiology, who argued that epidemiological studies, because they involve observations of humans and not animals, constituted the best evidence of causation. These experts observed that such studies on Bendectin had failed to show a causal link to most types of birth defects at a "statistically significant" 95% confidence level. Using this filter of "statistical significance" drawn from the field of epidemiology, then, Merrell argued that it was simply not possible to demonstrate that Bendectin is a teratogen — even though the underlying epidemiological studies, taken as a whole, generally revealed increased levels of birth defects in children of mothers who had taken Bendectin during pregnancy.

In September 1980, Merrell garnered some governmental support for the view that there was not yet sufficient proof that Bendectin was a teratogen. An FDA advisory committee convened largely at the behest of Merrell examined the available evidence in a two-day conference and endorsed this general outlook, "conclud[ing] that the relevant information 'did not demonstrate an increased risk of birth defects with Bendectin use,' but urg[ing] that studies be continued." *DeLuca, supra,* 911 F.2d at 943 (quoting committee conclusions).

3. Initial Procedural History of Case and Summary Judgment Denials

Petitioner was born on June 9. 1979, with grievous, multiple "limb reduction" birth defects. Her left leg is shortened, with minimal hip movement, a fixed knee, only one lower leg bone, and a deformed foot. Her right leg consists of a one-centimeter appendage. Her left arm consists of a short bone segment which tapers to a point. She has no right arm at all. Suit was instituted

on her behalf in 1980 on a variety of tort and contract grounds, alleging that her mother took Bendectin during the critical period when her limbs were forming, and that the Bendectin had caused her birth defects.

After discovery, in 1982 Merrell brought a motion for summary judgment on the issue of causation, filing elaborate and lengthy papers arguing that petitioner's case rested on "speculative evidence and opinions" that were not capable of proving causation. The District Court denied the motion, finding that a genuine issue of material fact existed. *See* Appendix D, at A13-A15. The District Court pointedly noted that the theory advanced for summary judgment "would effectively deprive any plaintiff of reaching the jury where the product at issue was not an accepted cause of birth defects or other diseases." A15.

Following unrelated proceedings on a procedural issue in the Court of Appeals and this Court during which the litigation was stayed,[3] Merrell renewed its motion for summary judgment, arguing again that no jury issue on causation was presented, citing recent cases in other jurisdictions where the jury had returned verdicts for the defense,[4] and relying heavily on

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[3] *See Koller* v. *Richardson-Merrell, Inc.*, 737 F.2d 1038 (D.C. Cir. 1984) (ruling in interlocutory appeal that District Court's order disqualifying plaintiff's counsel was invalid), *vacated and remanded*, 472 U.S. 424 (1985) (holding that such orders are not collateral orders subject to immediate appeal under 28 U.S.C. § 1291).

[4] Merrell prominently cited the multi-district common issues trial involving over 800 cases, *In re Richardson-Merrell, Inc. "Bendectin" Products Liability Litigation*, 624 F. Supp. 1212 (S.D. Ohio 1985), *aff'd*, 857 F.2d 290 (6th Cir. 1988), *cert. denied*, 488 U.S. 1006 (1989), in which the jury happened to decide that Bendectin does not cause birth defects — but in which Judge Rubin pointedly noted that "[b]oth sides presented testimony of eminently qualified and highly credible experts who differed in regard to the safety of Bendectin" and that the jury was confronted with "assess[ing] the credibility of each witness [to] resolve all conflicts of fact." *Id.* at 1244 (emphasis added). The Sixth Circuit agreed that "that the jury verdict following trial here might have been for the plaintiffs instead of for the defendant." 857 F.2d at 325.

this Court's "*Celotex* trilogy" liberalizing summary judgment practice. In 1986 the District Court reaffirmed its earlier ruling, finding "that there exists a genuine issue of material fact as to whether Bendectin caused Anne Koller's birth defects." Appendix F, at A20.

Petitioner concurrently brought a motion for partial summary judgment on causation arguing that Merrell should be collaterally estopped from denying that Bendectin *generally* is capable of causing birth defects, citing among other cases *Oxendine* v. *Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100 (D.C. 1986), *cert. denied*, 110 S.Ct. 1121 (1990), in which the D.C. Court of Appeals had upheld a $750,000 verdict against Merrell on far less evidence that proffered by petitioner.[5] Despite Merrell's prior day in court, the District Court held that "there is no basis in law to collaterally estop defendant from litigating the issue of causation in this action." Appendix E, at A19.

4. The *Richardson* and *Ealy* Decisions

Before trial, this case was stayed pending a decision by the Court of Appeals below in another case alleging harms from Bendectin, *Richardson* v. *Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S.Ct. 218 (1989), in which the Court of Appeals interpreted Fed. R. Evid. 703 as permitting a court to weigh the persuasiveness of the *conclusions* of competing expert witnesses, and exclude one side's

[5] In *Oxendine*, in which the plaintiff presented only one main witness and one rebuttal witness on causation, the trial court had granted judgment n.o.v. for Merrell after examining each item of evidence taken *alone* and finding insufficient evidence of causation. 506 A.2d at 1110. The D.C. Court of Appeals ruled that under the substantive law of the District, the trial court had erred "in failing to consider the [main] expert's testimony that all of the studies, *taken in combination*, did support" a finding of causation on the part of the jury. *Ibid.* (emphasis in original). It noted that in reviewing the nature of the evidence on a judgment n.o.v., "the court must view the evidence as a whole, not in fragments," because "[l]ike the pieces of a mosaic, the individual studies showed little or nothing when viewed separately from one another, but they combined to produce a whole that was greater than the sum of its parts." *Ibid.*

entire expert testimony on the ground that the conclusions are not "reasonable". The *Richardson* Court surveyed the current state of Bendectin evidence and ruled that unless new types of evidence emerge, expert opinion that Bendectin causes birth defects must be excluded because it is against the supposedly overwhelming weight of Merrell's epidemiological evidence to the contrary. *Richardson*, and the Court of Appeals' confirmatory opinion in *Ealy* v. *Richardson-Merrell, Inc.*, 897 F.2d 1159 (D.C. Cir.), *cert. denied*, 111 S. Ct. 370 (1990), were the sole basis for the Court of Appeals' summary disposition of this case below — rendering the earlier summary judgment motions irrelevant and denying petitioner a trial on the key scientific issues she raised. *See* Appendix A, at A1.

The *Richardson* trial court considered causation evidence from several plaintiffs' experts focusing on the standard four types of data relied on in the field of teratology and related fields: chemical structure analysis, and *in vitro*, *in vivo* and epidemiological data. Experts basing their conclusions on such data were opposed primarily by Merrell's epidemiological experts, who argued chiefly that the raft of studies to date had not demonstrated a "statistically significant" association between Bendectin and birth defects, and therefore it was impossible to prove causation. *Id.* at 826-27. After a jury verdict finding causation, the trial court sided with Merrell's experts and granted judgment n.o.v. on the conclusion that "no reasonable jury could find that [the plaintiff's] birth defects were more likely than not caused by Bendectin." *Id.* at 825.

The Court of Appeals affirmed the trial court on the theory that Rule 703 of the Federal Rules of Evidence required exclusion of all of plaintiffs' expert testimony.[6] Following the hold-

[6] In doing so the Court of Appeals sought to avoid potential problems under *Erie R.R.* v. *Tompkins*, 304 U.S. 64 (1938). As the plaintiffs had argued on appeal, and as the *Richardson* court acknowledged, *see* 857 F.2d at 825 n.9, the trial court's judgment n.o.v. was in tension with the recent *Oxendine*

ing of the First Circuit in *Lynch* v. *Merrell-National Laboratories Division of Richardson-Merrell, Inc.*, 830 F.2d 1190 (1st Cir. 1987), *aff'g*, 646 F. Supp. 856 (D. Mass. 1986), which affirmed a grant of summary judgment on causation based on Rule 703, the *Richardson* panel determined "that the epidemiological studies on Bendectin conclude[ ] overwhelmingly that the drug does not cause birth defects." 857 F.2d at 831.

In the *Richardson* trial, plaintiffs' experts had testified at trial without contradiction, in evident fulfillment of Rule 703, that experts in the field of teratology and related fields routinely and reasonably rely on all four types of data in drawing inferences about whether substances cause birth defects. Yet the *Richardson* panel opined, without analyzing the language or legislative history of Rule 703, that in making a Rule 703 determination, a court must "look behind [an expert's] ultimate conclusion . . . and analyze the adequacy of its foundation." *Id.* at 829.

The court explained that this involves not an assessment of whether experts rely on certain types of information in practice and whether it is generally reasonable to do so — irrespective of the conclusion ultimately arrived at — but rather an assessment of the court's view of the *weight of the opinion* derived from this information, compared with the weight of contrary opinion on the other side. The *Richardson* court's theory was that the existence of numerous epidemiological studies, individually failing to conclude with *95% confidence* that Bendectin causes birth defects, *id.* at 831, somehow negates the other

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case, *see supra* note 5, holding that under the substantive law of the District of Columbia the four types of evidence relied on by plaintiffs' experts could easily support a jury finding of causation. The Court of Appeals stated that "*Erie* does not affect the federal courts' application of the Federal Rules of Evidence," *ibid.*, and concluded that inasmuch as the question of adequate basis under Rule 703 was an "issue[ ] of law falling within the province of the court," the function of the jury was not being usurped. *Id.* at 833.

probative information relied on by the plaintiffs' experts, and therefore the foundation could not be adequate. *Id.* at 830, 832.

In *Ealy*, a year and a half later a separate panel of the D.C. Circuit confirmed and cemented the *Richardson* holding, announcing that, on the basis of current scientific knowledge, all future Bendectin litigation in the Circuit will be barred, because *as a matter of law* no expert opinion finding causation is even admissible in evidence.

Ealy involved Merrell's appeal from a trial judge's *refusal* to set aside a jury verdict in favor of the plaintiffs. Merrell argued "that the *Richardson* decision provides a binding legal precedent that requires reversal of the trial court's denial of its motion for judgment n.o.v." 897 F.2d at 1161. The plaintiffs responded that an evidentiary ruling in a separate case to which they were not a party or privy could not possibly apply to them, that they were entitled to have evidence admissibility issues evaluated on the record in *their* case alone, and that, in admitting their expert opinion evidence, the trial judge had agreed with the uncontradicted testimony of their experts that the types of data being relied on are typically and reasonably relied upon in the field of teratology and related fields.

The *Ealy* court nonetheless announced that *Richardson* would henceforth be treated as articulating a "binding legal rule," applicable to *all* cases, because "an expert opinion that Bendectin is a human teratogen which caused the plaintiff's birth defects is without scientific foundation under Federal Rule of Evidence 703 in the face of 'a wealth of published epidemiological data' to the contrary." *Id.* at 1160 (citing *Richardson*, 857 F.2d at 832). The *Ealy* court further elaborated:

> The *Richardson* court concluded, as a matter of law, that the "wealth of published epidemiological data . . . none of which has concluded that the drug is teratogenic . . . must be given their just due." 857

> F.2d at 832. Therefore, under Rule 703, an opinion refuting this scientific consensus is inadmissible for lack of an adequate foundation, in the absence of other substantial probative evidence on which to base this opinion. It is this uncontroversial rule of evidence that is the *ratio decidendi* of *Richardson* and this case.

897 F.2d at 1162.[7]

In sum, the *Ealy* court ruled that the large number of *published, peer-reviewed* epidemiological studies all *failing* to indicate with 95% confidence that Bendectin causes birth defects "must be recognized as the measuring stick for the admissibility of expert testimony on this issue," that this makes the conclusions of plaintiffs' experts not "reasonable" and hence inadmissible under Rule 703, and that only if stronger "new epidemiological or other types of data" are generated by scientific research may Bendectin plaintiffs litigate their claims. *Id.* at 1163-64. As *Ealy* makes clear, the D.C. Circuit's interpretation of Rule 703 permits it to force the exclusion of evidence in any type of case where a panel believes that expert opinions reaching one set of conclusions are sufficiently outweighed by expert opinions on the other side.

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[7] The *Ealy* court further observed: "Because *Richardson* provides a binding legal precedent governing the admissibility of expert opinion on the ability of Bendectin to cause human birth defects, the Ealys can only avoid that decision by showing that the record here is materially different from *Richardson*." 897 F.2d at 1162. The court found no such difference, given that *most* of the studies relied on by the Ealys' experts were "virtually the same" as *Richardson* and that the *new* data presented had "dubious significance in the face of the epidemiological data." *Id.* at 1162-63.

The *Ealy* court again turned aside the *Erie* objection, *see supra* note 6, explaining that "this case, like *Richardson*, turns on the admissibility of the expert opinion testimony," and that it was "enforcing a procedural rule governing admissibility" and "not supplanting substantive state rules on the sufficiency of evidence." *Id.* at 1163.

5. The District Court's Decision Below

After *Richardson* was decided, but before *Ealy* was handed down, on Merrell's motion the District Court below ordered petitioner to show cause why the case should proceed, and specifically asked petitioner to identify expert opinion testimony that would meet the strictures announced in *Richardson*. In response petitioner exhaustively detailed the proposed testimony of her sixteen expert witnesses in support of causation, and chronicled the large number of cases where such testimony had been accepted nationwide in federal courts as creating a jury issue; argued that *Richardson* could not be squared with the Federal Rules of Evidence; and argued that the *Richardson* holding could not be binding on petitioner and that she had a right to her own day in court.

In its memorandum opinion the District Court reviewed the *Richardson* holding and concluded that the Court of Appeals had "found, as a matter of law, that expert opinion testimony, which relies upon chemical structure analysis, *in vivo, in vitro* studies, or reformulated epidemiological data, is not admissible," and that therefore "the issue of causation shall not be presented to a jury unless the plaintiffs offer scientific evidence other than that which has heretofore been proffered." (A8-A9). Thus, despite its earlier two rulings upholding petitioner's right to present her case to a jury, the District Court was constrained by the *Richardson* rule within the D.C. Circuit to grant judgment in favor of the defendant. (A9).

6. The Court of Appeals' Decision Below

Petitioner appealed, again arguing in detail that her extensive expert testimony on causation plainly met the admissibility requirements of the Federal Rules of Evidence, and that binding her to the *Richardson* holding violated the Rules and was unconstitutional. The case was held pending the decision in *Ealy*, and thereafter Merrell moved for summary affirmance.

In a one-page *per curiam* order announced on August 31, 1990, a third, entirely separate panel of the Court of Appeals granted that motion, "substantially for the reasons stated by the district court in its memorandum opinion filed June 30, 1989," and cited both *Richardson* and *Ealy*. (A1-A2). A petition for rehearing and for rehearing *en banc* was filed, emphasizing the unconstitutionality of dismissing the case on this record and urging the Court of Appeals to reconsider its interpretation of Rule 703 and the admissibility of Bendectin evidence in light of the Third Circuit's recent opinion explicitly rejecting the approach of *Richardson* and *Ealy*, in *DeLuca, supra*, 911 F.2d at 950. The petitions were denied on November 7, 1990. (A11-A12).

REASONS FOR GRANTING THE WRIT

I. The decision below flouts the plain statutory language and purpose of Fed. R. Evid. 703, and reveals the need for this Court to resolve the long-standing circuit conflict over Rule 703

The Court of Appeals below, as well as the First Circuit, has interpreted Rule 703 of the Federal Rules of Evidence to give lower federal courts broad authority to decide ultimate issues of scientific fact, by weighing competing expert testimony in the context of making admissibility decisions. Nothing could be further from the clear language and purpose of the Rule, as the Third Circuit has recently summarized in its latest Bendectin case, expressly rejecting the First Circuit's *Lynch* decision and the decisions of the court below in *Richardson* and *Ealy*, and explaining that under Rule 703 the weight and relative persuasiveness of an expert's conclusions are irrelevant. *See DeLuca* v. *Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 952-54 (3d Cir. 1990). The plenary atten-

tion of this Court is warranted both to correct this egregious construction of Rule 703 and to resolve the more general conflict in the circuits over the meaning of Rule 703, which has resulted from the lower courts' failure to heed this Court's instructions for construing the Federal Rules of Evidence.

Unlike the Federal Rules of Civil Procedure and other rules governing the federal courts, the Federal Rules of Evidence are purely creatures of statute. Concerned about the drafting and promulgation of the Rules by the Judiciary, Congress took over the process, made a variety of revisions in the draft, and enacted the rules as a statute. Accordingly, as this Court has unanimously emphasized, "[b]ecause the Federal Rules of Evidence are a legislative enactment, we turn to the 'traditional tools of statutory construction,' in order to construe their provisions." *Beech Aircraft Corp.* v. *Rainey*, 109 S. Ct. 439, 446 (1988) (citation omitted).[8] The starting point, of course, is the language of the Rules themselves. *Ibid.*; *see also Pennsylvania Dep't of Public Welfare* v. *Davenport*, 110 S. Ct. 2126, 2130 (1990). Moreover, "in all cases of statutory construction, [a court's] task is to interpret the words of . . . statutes in light of the purposes Congress sought to serve," as revealed in the legislative history. *Chapman* v. *Houston Welfare Rights Org.*, 441 U.S. 600, 608 (1979).

In enacting the Federal Rules of Evidence, Congress made a fundamental policy choice in its treatment of expert testimony — a policy choice that the court below utterly ignored and overrode, and one that bears heavily on the proper interpretation of Rule 703. Congress embraced deliberately receptive standards for admissibility of expert testimony, making a decision to allow the testimony of any knowledgeable expert

[8] This Court has of course consistently used this traditional approach in its decisions interpreting the Federal Rules of Evidence, rejecting policy-based arguments in construing the Rules. *See generally* Jonakait, *The Supreme Court, Plain Meaning, and the Changed Rules of Evidence*, 68 Tex. L. Rev. 745 (1990).

having specialized information that might assist a jury — and to have the relative weight of testimony thrashed out in the adversary process before the jury.

In doing so, Congress displaced the restrictive, distrustful approach to expert testimony developed over decades by the Federal Judiciary through a common-law approach. Under these rules, for example, an expert was often forced to testify through use of hypothetical questions, thereby limiting the bases of his or her testimony to otherwise admissible evidence; usually an expert could not opine on an "ultimate issue" for fear of invading the province of the jury; and notably under the rule of *Frye* v. *United States*, 293 F. 1013 (D.C. Cir. 1923), courts also insisted that expert testimony be based on a methodology enjoying "general acceptance in the particular field in which it belongs," *id.* 1014, thus incorporating a method of peer review for underlying scientific theories.

Such common-law restrictions endured decades of criticism from courts and commentators alike.[9] As Judge Weinstein has noted, their approach "in practice was often stilted, awkward and unduly restrictive." Weinstein, *Improving Expert Testimony*, 20 U. Rich. L. Rev. 473, 476 (1986). "As technology advanced and expert testimony became more important in the resolution of increasingly complex litigation, unnecessary impediments became unacceptable," and in particular, "it became clear that the *Frye* rule might block the introduction of important and useful testimony." *Id.* at 476-77.

Passage of the Federal Rules of Evidence revolutionized expert testimony. "With little discussion, Congress adopted the opinion rules in nearly the same form as the advisory com-

[9] "Wigmore, McCormick, and other eminent commentators . . . complained for decades about common-law restrictions on opinion evidence that deprived triers of fact of valuable information needed for sounder adjudications." Berger, *United States* v. *Scop: The Common Law Approach to an Expert's Opinion About a Witness's Credibility Still Does Not Work*, 55 Brooklyn L. Rev. 559, 559 (1989).

mittee proposed," which "is perhaps understandable since the rules reflect an enlightened, academic view of opinion testimony that dates back some fifty years." Pratt, *A Judicial Perspective on Opinion Evidence Under the Federal Rules*, 39 Wash. & Lee L. Rev. 313, 314 & n.5 (1982) (citing authorities). The scheme "rel[ies] heavily on the adversary system," and trusts the ability of counsel to present such testimony and of juries to evaluate it. *Id.* at 313. The goal "[t]hat evidence scholars had long been seeking ha[s] now come to pass." Weinstein, *supra*, at 477.

The central expert testimony provision is of course Rule 702; Rule 703 plays a relatively minor role. Under Rule 702, a broad range of persons may qualify as "experts," by virtue of "knowledge, skill, experience, training, or education". As to substance, testimony is permitted as long as "scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or determine a fact in issue."

Rule 702 therefore greatly expands the admissibility of expert testimony, and under it "[a]ny relevant conclusions supported by a qualified expert witness should be received." E. Cleary, *McCormick on Evidence* § 203, at 608 (3d ed. 1984). As the Third Circuit has emphasized, the policy judgment reflected in the Rules "embod[ies] a strong and undeniable preference for admitting any evidence having *some* potential for assisting the trier of fact and for dealing with the risk of error through the adversary process." *DeLuca*, 911 F.2d at 956 (citing *Barefoot* v. *Estelle*, 463 U.S. 880, 899 & 901 n.7 (1983)) (emphasis added).

Despite the clear policy choice made by Congress, the court below has endeavored to construe Rule 703 to give federal courts *carte blanch* to exclude expert opinion testimony based on its relative weight compared with opposing testimony. This view, however, simply flouts the plain language of Rule 703, which makes obvious that the function of the Rule is to expand

available expert testimony *beyond* Rule 702 and streamline trials, by allowing experts to function as they do in everyday work, drawing on their supply of background knowledge in a given field as well as relevant literature, even if this information is inadmissible in evidence.

The text of Rule 703 could not be clearer: as long as the "facts or data" on which an expert bases his or her opinion are "of a type reasonably relied upon by experts *in the particular field* in forming opinions or inferences upon the subject," there is no need for the facts or data to be admissible into evidence (emphasis added). As the Advisory Committee Note to Rule 703 explains, this aspect of "the rule is designed to *broaden* the basis for expert opinions beyond that current in many jurisdictions and to bring the *judicial practice* into line with the *practice of the experts* themselves when not in court" (emphasis added). Notably, the words "in the particular field" were added to Rule 703 in the later stages of drafting in recognition of the fact that the types of data relied on by experts vary among fields.[10]

The whole point of the Rule is thus to modify courtroom procedures to accommodate the customary practice of experts — not to give courts a tool for excluding an expert's conclusions based on a court's perception, in light of the court's own subjective view of the persuasiveness of the underlying data, that is not "reasonable" for the expert to express a given view. The court below, however, totally misapplied Rule 703 by barring *teratologists* from basing opinions in part on

[10]The 1969 version lacked the words "in the particular field." Proposed Rules of Evidence, 46 F.R.D. 161, 315 (1969). The phrase was added on the suggestion of a bar group. American College of Trial Lawyers, *Report of the Comm. to Study the Proposed Rules of Evidence* (1970) ("In Rule [703], concerning expert opinion testimony, it would be desirable in dispensing with facts or data supporting such an opinion to require that the underlying facts or data be of a type reasonably relied upon by an expert versed in the particular field, rather than by experts generally.").

epidemiological evidence not meeting strict tests of "statistical significance" even though they do so in their common practice, merely because experts in *another* field, that of epidemiology, do not do so in *their* common practice.

The Court of Appeals below has never defended its reading of Rule 703 against the analysis of the Third Circuit in the most widely noted case on the issue, *In Re Japanese Electronic Products Antitrust Litigation*, 723 F.2d 238 (3rd Cir. 1983), *rev'd on other grounds sub nom. Matsushita Elec. Indus. Co.* v. *Zenith Radio Corp.*, 475 U.S. 574 (1986). There, the District Court refused to admit into evidence expert antitrust reports or live opinions concerning them, despite uncontradicted affidavits establishing that the data in them were reasonably relied upon by experts in the relevant fields. The District Court proceeded on the policy assumption that, under Rule 703, "given the potential for open-ended receipt into evidence of testimony based upon information of questionable reliability, it is plain that some limitation on the types of information upon which an expert may rely is essential," and that "the judge must be the ultimate arbiter of the reliability of materials upon which an expert witness bases his opinion." *Zenith Radio Corp.* v. *Matsushita Elec. Indus. Co.*, 505 F. Supp. 1313, 1323, 1326 (E.D. Pa. 1980).

The Third Circuit disagreed. It found that "the trial judge misapplied Rule 703 in concluding that he, not the experts in the field, was the source of information about reasonable reliance," 723 F.2d at 280. In a thorough review of the language and history of the provision, the Court of Appeals made amply clear that, where there is a dispute under Rule 703, a trial court must determine the issue *on the trial record before it*, and "[t]he proper inquiry is not what the *court* deems reliable, but what experts in the relevant discipline deem it to be. . . . [T]he district court must make a *factual* inquiry and finding as to *what data experts in the field find reliable*." *Id.* at 276-77

(emphasis added). It explained that the roots of Rule 703 run too deep to allow room for policy adjustments by the courts:

> The indice of reliability under Rule 703 is the fact that experts in the field in question rely on the type of data in forming their opinions. . . . It was this view which the drafters incorporated in Rule 703. They did so over significant opposition. What the trial court did in effect was to reject the decision of the Judicial Conference, the Supreme Court, and Congress and adhere to an unusually restrictive view as to the basis on which an expert's opinion may be laid.

Id. at 277 (citation omitted). Instead, the Court of Appeals encouraged vigorous cross-examination of experts, noting that "the factfinder can be expected to determine the appropriate weight to be given to the testimony." *Id.* at 277-78.

Nor did the Court of Appeals below, in granting summary affirmance in this case, take any account of the Third Circuit's specific Rule 703 opinion in a Bendectin case, *DeLuca*, which explained the illegitimacy of *Richardson, Ealy* and *Lynch*. The *DeLuca* trial court had relied on *Richardson* to rule the plaintiffs' causation evidence inadmissible based on Merrell's recitation of "the great weight of scientific opinion in its favor" as revealed in the few cases in other courts in which Merrell had won summary judgment. 911 F.2d at 944. The trial court excluded the testimony "despite the fact that most of the data relied upon by [the plaintiffs' expert] was data from peer reviewed articles in medical journals" relied upon by Merrell's own expert. *Ibid.*

Reaffirming its landmark *Japanese Antitrust* decision, see *id.* at 952-53 — and illustrating and opining on the sharp conflict among the circuits over whether whole categories of "mass toxic tort" cases can be dismissed based on the mere

absence of "statistically significant" studies — in *DeLuca*, the Third Circuit rejected *Richardson's* and *Ealy's* focus on the *weight* of expert testimony, holding it legally irrelevant to the inquiry mandated by Rule 703:

> [W]e do not view the absence of statistically significant findings or the great weight of contrary opinion as being relevant to the Rule 703 question posed here. *Rule 703 is satisfied once there is a showing that an expert's testimony is based on the type of data a reasonable expert in the field would use* in rendering an opinion on the subject at issue; it does not address the reliability or general acceptance of an expert's methodology.

Id. at 953 (emphasis added). Although the Third Circuit shared *Richardson's* concern about potential abuses "whenever an expert is permitted to testify to an opinion that is based upon reasoning and data that have not been subjected to the review of professional colleagues," it held that "we may not manipulate our interpretation of the Federal Rules of Evidence to exclude expert testimony" nor "impose special burdens of proof on Bendectin plaintiffs . . . ." *Id.* at 952.

Despite the Third Circuit's clear guidance on the meaning of Rule 703, the Court of Appeals below and the *Lynch* court are not the first courts of appeals to misinterpret Rule 703. Although the Third Circuit has been followed by the Fourth,[11] the Sixth,[12] the Seventh,[13] and the Eighth,[14] several other cir-

[11] *Clinchfield Railroad Co.* v. *Lynch*, 784 F.2d 545, 554 (4th Cir. 1986).

[12] *AU Rustproofing Center, Inc.* v. *Gulf Oil Corp.*, 755 F.2d 1231, 1238 (6th Cir. 1985); *Mannino* v. *International Mfg. Co.*, 650 F.2d 846, 851-53 (6th Cir. 1981).

[13] *United States* v. *Bramlet*, 820 F.2d 851, 856 (7th Cir.), *cert. denied*, 484 U.S. 861 (1987); *United States* v. *Lundy*, 809 F.2d 392, 395-96 (7th Cir. 1987).

[14] *Hurst* v. *United States*, 882 F.2d 306, 311 (8th Cir. 1989); *Cashman* v. *Allied Products Corp.*, 761 F.2d 1250, 1255 (1985).

cuits have followed the lead of the District Court in the *Japanese Antitrust* case in second-guessing the reasonableness of the types of data on which experts in fact rely: namely, the Second Circuit,[15] a number of decisions in the Fifth Circuit,[16] and at least one decision in the Tenth Circuit.[17]

There is thus a clear, persistent and important conflict in the circuits over the construction of Rule 703 — a rule relevant to virtually every federal trial involving expert testimony. This split over the meaning of Rule 703 cannot be allowed to fester any longer. The Senate Report accompanying the bill that became the Federal Rules of Evidence cited the need for "a comprehensive code of evidence intended to govern the admissibility of proof in all trials before the Federal courts because of the lack of uniformity and clarity in the present law of evidence on the Federal level." S. Rep. No. 93-1277, 93rd Cong., 2d Sess. (1974), at [1974] U.S. Code Cong. & Ad. News 7054. That legislative aim plainly cannot be maintained unless this Court resolves persistent circuit conflicts over rules that are integral to large numbers of trials conducted each day throughout the Nation.

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[15] *United States* v. *Daly*, 842 F.2d 1380, 1387 (2d Cir.), *cert. denied*, 109 S.Ct. 66 (1988); *Shatkin* v. *McDonnell Douglas Corp.*, 727 F.2d 202, 208 (2d Cir. 1984) (holding that District Court had "the discretionary right under Fed.R.Evid. 703 to determine whether the expert acted reasonably in making assumptions of fact upon which he would base his testimony").

[16] *E.g.*, *Washington* v. *Armstrong World Indus.*, 839 F.2d 1121, 1123 (5th Cir. 1988), and *Viterbo* v. *Dow Chemical Company*, 826 F.2d 420, 422 (5th Cir. 1987) (allowing independent scrutiny of reliability). The Fifth Circuit seems very much in conflict with itself on this issue. *Compare Christopherson* v. *Allied-Signal Corp.*, 902 F.2d 362, 364 (5th Cir. 1990), and *Peteet* v. *Dow Chemical Co.*, 868 F.2d 1428, 1432 (5th Cir. 1989) (appearing to apply more liberal standard), *cert. denied*, 110 S.Ct. 328.

[17] *Head* v. *Lithonia Corp.*, 881 F.2d 941, 943-44 (10th Cir. 1989). This may be the minority view in the circuit. *Compare Wilson* v. *Merrell Dow Pharmaceuticals*, 893 F.2d 1149, 1153-55 (10th Cir. 1990) and *Marsee* v. *United States Tobacco Co.*, 866 F.2d 319, 323 (10th Cir. 1989) (both taking more liberal approach).

II. The decision below rests on common-law evidence rulemaking that is incompatible with the Federal Rules of Evidence

Even if the construction of *Rule 703* reached by the Court of Appeals below had any merit and could be applied in an individual case, the Federal Rules of Evidence as a whole plainly bar the courts of appeals from ordering trial judges to exclude, as a "matter of law," particular expert conclusions in entire categories of *future* cases.

Rule 401 defines "relevant evidence" as "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." (Emphasis added.) Rule 402 states the broad policy of the Federal Rules of Evidence — expansive admissibility — *and* itemizes the only grounds for excluding evidence:

> All relevant evidence is admissible, *except* as otherwise provided [1] by the Constitution of the United States, [2] by Act of Congress, [3] by these rules or [4] by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

(Emphasis and brackets added). Finally, Rule 104(a) requires that admissibility decisions under Rule 402 be made by the *trial* court *on the record* in the *individual* case; this allocation of judicial authority clearly applies to Rule 703 determinations.[18]

The pre-1975 freedom of the federal appellate courts to create *ad hoc* common-law evidence rules is therefore gone,

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[18] The court below ignored hornbook law that "[t]he question whether reliance by an expert is reasonable as required by FRE 703 involves a factual judgment to be made by the trial judge pursuant to Rule 104(a)." 3 D. Louisell & C. Mueller, *Federal Evidence* § 389, at 418 (West Supp. 1988) (citations omitted).

for Rule 402 does not authorize federal courts to impose new exceptions on admissibility. In exercise of its undoubted power to supplant judge-made procedure,[19] and to secure nationwide uniformity in evidence law, *see supra* p. 25, Congress has thus stripped the federal courts of the authority to promulgate the type of customized admissibility limits imposed by the court below.[20] The only exception to uniformity is found in Rule 501, which permits common-law development of privilege doctrine "in the light of reason and experience" — indicating that Congress's failure to authorize the courts of appeals to dictate exclusion "as a matter of law" was a deliberate one.

III. The decision below is unconstitutional because federal courts are barred from employing the Rules of Evidence to pronounce conclusions about ultimate scientific fact that bind absent third parties on state law issues.

Regardless of the authority under the Federal Rules of Evidence for the order of the court below, the D.C. Circuit's approach violates three key constitutional guarantees in federal court cases involving state tort law.

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[19] Even the power of *this* Court "to prescribe rules of procedure and evidence for the federal courts exists only in the absence of a relevant Act of Congress," *Palermo* v. *United States*, 360 U.S. 343, 353 n.11 (1959). Under the Necessary and Proper Clause, "Congress has undoubted power to regulate the practice and procedure of federal courts." *Sibbach* v. *Wilson & Co.*, 312 U.S. 1, 9 (1941).

[20] *See* Imwinkelried, *The Meaning of Probative Value and Prejudice in Federal Rule of Evidence 403: Can Rule 403 Be Used to Resurrect the Common Law of Evidence?*, 41 Vand. L. Rev. 879, 881-83 (1988); Weissenberger, *The Former Testimony Hearsay Exception: A Study in Rulemaking, Judicial Revisionism, and the Separation of Powers*, 67 N. Car. L. Rev. 293, 33134 (1989). Quite apart from Rule 402, in the sphere of federal judge-made law this Court adopts a *presumption* that relevant legislation displaces past judge-made rules. Congress displaces federal judge-made law simply by comprehensively addressing a particular matter — here, admissibility of expert testimony — and *failing* to preserve judge-made law. *Milwaukee* v. *Illinois*, 451 U.S. 304, 315 (1981) (citation omitted).

(1) Under the Seventh Amendment both parties are entitled to have a jury resolve disputed issues of historical and scientific fact. "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of the judge." *Anderson* v. *Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). The D.C. Circuit's creative use of Rule 703 to work a takeover of these essential functions plainly violates the Seventh Amendment, for it has no conceivable analog to procedural law circa 1791. *Parklane Hosiery Co.* v. *Shore*, 439 U.S. 322, 336-37 (1979). Yet the whole point of the Seventh Amendment is to check the power of the federal courts by placing cases in the hands of people other than the sovereign's judges, no matter how inefficient this can be. See id. at 337-56 (Rehnquist, J., dissenting); *see also Granfinanciera, S.A.* v. *Nordberg*, 109 S. Ct. 2782, 2813 (1989) (White, J., dissenting) ("The function of the civil jury is to diffuse the otherwise autocratic power and authority of the judge").

(2) Both parties, of course, are entitled to be represented at a hearing, to have their day in court during which they can present probative evidence, and to have decision of factual issues based on *their* record — regardless of how many other litigants have raised similar issues and how much more efficient it might be to bind them to the results of past cases. *E.g.*, *Martin* v. *Wilks*, 109 S. Ct. 2180, 2184-88 (1989); *Blonder-Tongue Laboratories, Inc.* v. *University of Illinois Foundation*, 402 U.S. 313, 329 (1971). Yet plaintiffs in the D.C. Circuit are told simply that the conclusions that *their* experts pronounce have already been considered through the proxy of *other* litigants and experts, in an earlier case, and were rejected as outweighed by supposedly contradictory evidence — and that these later plaintiffs are bound by this earlier factual assessment. Petitioner litigated for a decade, and survived two summary judgment motions, only to be told that her claims had al-

ready been heard and rejected. In effect the D.C. Circuit imposed a surprise, mandatory class action to decide whether Bendectin is a teratogen, and bound all future plaintiffs without any of the procedural protections that would be afforded under an actual class action. *Cf. Phillips Petroleum Co.* v. *Shutts*, 472 U.S. 797, 811-12 (1985).

(3) The relevant Article III courts must limit themselves to adjudicating "cases or controversies" and must not disregard the state substantive law that controls the case. In Bendectin cases the D.C. Circuit has functioned instead like "a sort of junior-varsity Congress," *Mistretta* v. *United States*, 109 S. Ct. 647, 683 (1988) (Scalia, J., dissenting), enacting its own legislative fact findings and conclusive presumptions for the District of Columbia, evading the constraints on such activity in Fed. R. Civ. P. 201. Mistakenly relegating federalism concerns to the status of "*Erie*" problems that can be avoided under the authorization of the Rules Enabling Act, *see supra* notes 5, 6, & 7, the D.C. Circuit has manipulated a self-contained federal statute — the Federal Rules of Evidence — to completely displace District of Columbia tort law, without any clear statement from Congress that this is permissible.

Acknowledgement of these three elementary principles in the context of "mass tort" cases has varied. Inspired by the D.C. Circuit's *Richardson* holding, a panel of the Fifth Circuit violated all three in *Brock* v. *Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166, *reh'g denied*, 884 F.2d 167 (5th Cir. 1989), *cert. denied*, 110 S. Ct. 1511 (1990). Professing a need to confront the "special problems and challenges to traditional ideas regarding the role of the jury as a decisionmaker" in "mass tort" cases, the Court of Appeals found it important to prevent juries from splitting "both ways" on common factual issues that "may be just a matter of opinion," in order to avoid "a sub-optimal amount of new drug development," and consequently it proclaimed

that judgment n.o.v. must be entered against all future Bendectin plaintiffs lacking "statistically significant" causation evidence. *Id.* 309-10, 315. While expressing sympathy with such policy concerns, the Third Circuit in *DeLuca* adhered to all three principles and rejected *Brock*'s and the D.C. Circuit's customized approach to Bendectin cases. 991 F.2d at 950-52.

Judge Patrick Higgenbotham, writing for the Fifth Circuit, honored these principles in the context of the far more burdensome asbestos litigation, by rejecting a District Court's plea that a quasi-administrative scheme, which would have denied defendants Seventh Amendment and due process rights in thousands of cases and displaced state tort law policy choices, was necessary to resolving these cases. *In re Fibreboard Corp.*, 893 F.2d 706 (5th Cir. 1990). Suggesting that the representative branches be consulted, he apologized that "[t]he Judicial Branch can offer the trial of lawsuits. It has no power or competence to do more." *Id.* at 712.

The lower federal courts would benefit from reaffirmation of these central principles in the "mass tort" context. At minimum, the exercise of this Court's supervisory power is warranted to halt the D.C. Circuit's aberrant use of the Federal Rules of Evidence to deny the statutory and constitutional rights of plaintiffs, and to settle the disagreement among the courts of appeals on these basic questions.

CONCLUSION

For the reasons stated above, a writ of certiorari should be granted.

Respectfully submitted,

KENNETH J. CHESEBRO
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February 5, 1991

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APPENDIX A

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 89-7167 September Term, 1989

C.A. No. 80-01258

Filed Aug. 31 1990

ANNE ELISABETH KOLLER,
APPELLANT

v.

RICHARDSON-MERRELL, INC.

BEFORE: Ruth B. Ginsburg, Buckley and Sentelle, Circuit Judges

ORDER

Upon consideration of appellee's motion for summary affirmance, the response thereto, and the reply, and appellant's motion to strike, it is

ORDERED that the motion to strike be denied. It is

FURTHER ORDERED that the motion for summary affirmance be granted substantially for the reasons stated by the district court in its memorandum opinion filed June 30, 1989. *See also Ealy v. Richardson-Merrell, Inc.*, 897 F.2d 1159 (D.C. Cir. 1990), *petition for cert. filed*, 59 U.S.L.W. 3095 (U.S. Aug. 1, 1990) (No. 90-225); *Richardson v. Richardson-Merrell, Inc.*, 856 F.2d 823 (D.C. Cir. 1988), *cert. denied*,

110 S. Ct. 218 (1989). The merits of the parties' positions are so clear as to justify summary action. *See Taxpayers Watchdog, Inc. v. Stanley*, 819 F.2d 294, 297 (D.C. Cir. 1987) (per curiam); *Walker v. Washington*, 627 F.2d 541, 545 (D.C. Cir.) (per curiam), *cert. denied*, 449 U.S. 994 (1980).

The Clerk is directed to withhold issuance of the mandate herein until seven days after disposition of any timely petition for rehearing. *See* D.C. Cir. Rule 15.

Per Curiam

APPENDIX B

United States District Court

FOR THE DISTRICT OF COLUMBIA

ANNE ELISABETH KOLLER,
et al.,
PLAINTIFFS,

Civil No. 80-1258

VS.

RICHARDSON-MERRELL, INC.
DEFENDANT.

Filed June 30, 1989

MEMORANDUM OPINION

Bendectin, a prescription drug manufactured by defendant, Richardson-Merrell Inc.,[1] to ease the nausea and vomiting often associated with pregnancy, has been the subject of numerous lawsuits. In this case, plaintiffs, Anne Elisabeth Koller and her parents, John Lamont and Cynthia Anne Koller, filed a complaint alleging that the ingestion of Bendectin by the mother during her pregnancy caused the minor plaintiff to be born with severe birth defects. Following the completion of discovery but before trial, this action was stayed pending a decision by the United States Court of Appeals for the District of Columbia Circuit in a case involving an identical question of law. That decision was rendered on September 27, 1988, and styled *Richardson v. Richardson-Merrell*, 857 F.2d 823 (D.C. Cir. 1988). The Court will now address the effect of the *Richardson* decision on the instant action.

[1] Richardson-Merrell, Inc. is now doing business as Merrell Dow Pharmaceuticals, Inc.

BACKGROUND

This case, filed in 1980, was finally scheduled for trial after the *Richardson* case. Aware of the significance of the holding in that case, a stay was granted on the motion of defendant pending the decision of the Court of Appeals.

On October 14, 1988, following the decision in *Richardson*, defendant moved to have the stay lifted and for an order to have plaintiffs show cause why this case should proceed in light of the holding in that case. This motion was granted, and the plaintiffs were directed to identify specific, admissible, expert evidence of a causal relationship between Bendectin and limb defects which would meet the standards announced in the *Richardson* decision.

Plaintiffs responded to the Order to Show Cause, arguing, in the first instance, that the *Richardson* case is not controlling over this action, and in the alternative, that the Court should permit a jury to consider the evidence adduced by plaintiffs to prove causation. Defendant argues that the *Richardson* decision is dispositive; that all of the evidence proffered by plaintiffs to demonstrate a causal link between Bendectin and Anne's limb defects has been declared inadmissible by the Court of Appeals in the *Richardson* case.

DISCUSSION

Before deciding whether plaintiffs may proceed to trial on the evidence proffered in their 26(b)(4) statements filed on December 15, 1982, an analysis of the *Richardson* decision is warranted. The jury in that case, after hearing the testimony of experts presented by both plaintiffs and defendants, found that Bendectin is a human teratogen and capable of causing birth defects in humans. It further concluded that Bendectin was the proximate cause of the birth defects experienced by the

minor plaintiff in *Richardson*. The trial court granted the motion of defendant for judgment *non obstante veredicto* and found that a reasonable jury could not conclude, based upon the evidence presented by plaintiffs at trial, that a causal connection between Bendectin and limb defects existed. In the alternative, the court granted the motion of defendants for a new trial.

The Court of Appeals affirmed the decision of the trial judge. It concluded that while the issue before it is scientific in nature and "expert witnesses are indispensable," the Court need not "accept uncritically any sort of opinion espoused by an expert merely because his credentials render him qualified to testify." *Richardson, supra,* at 829. The Court found that in order for evidence to be presented to a jury it must be "a type reasonably relied upon by experts in the particular field . . ." and should not be given to a jury if it "only 'provides a mere possibility yet not a probability of proof.' " *Id.* (quoting *Marder v. G.D. Searle & Co.*, 630 F. Supp. 1087, 1093-94 (D. Md. 1986), *aff'd without opinion sub nom. Wheelahan v. G. D. Searle & Co.*, 814 F.2d 655 (4th Cir. 1987).

The Court then analyzed the various types of evidence presented by the plaintiffs' primary expert witness, Dr. Alan K. Done. The court's purpose in so doing was to determine if there is a scientifically sound foundation to support his testimony that there is a causal connection between ingestion of Bendectin during pregnancy and birth defects.

Dr. Done relied upon four different types of studies to reach his conclusion: 1) chemical structure activity analysis; 2) *in vivo* studies; 3) *in vitro* studies; and 4) recalculated data from epidemiological studies. The Court analyzed each one to determine their scientific reliability.

Beginning with the chemical structure studies, the Court of Appeals noted that the investigation by Dr. Done of Bendectin's chemical structure revealed similarities between the anti-

histamine component of the drug and other antihistamines which have been found to cause birth defects in animals. The Court found, however, that the effect of these antihistamines on humans has not been determined. Moreover, chemical structure analysis, as a scientific methodology, was found to provide little proof of causation. "As Dr. Done acknowledged, the purposes of analyzing chemical structures is to indicate what other directions a study of a substance should take; in other words, chemical structure activity analysis 'gives you a clue,' or 'raises at least a flag to you indicating that this is a drug that you ought to and must study for teratologic effect . . .'" *Id.* at 830 (quoting the Trial Transcript at 798). From this conclusion, the Court determined that the chemical structure studies relied upon by Dr. Done to support his testimony were not valuable.

Turning to the *in vitro* (animal) studies used by Dr. Done, the Court of Appeals found that the doctor's own testimony supported a conclusion that while animal studies are useful in determining if further tests should be performed, they, like chemical structures studies, "serve merely to raise a suspicion regarding the effect of Bendectin on humans . . ." *Id.* Consequently, this evidence cannot, in a court of law, serve as a foundation for the doctor's expert opinion.

A similar conclusion was reached with respect to *in vitro* (test tube) studies. Again, the Court of Appeals concluded that "the value of such an examination as a predictor of human teratogenicity is extremely meager . . ." *Id.* Having assessed the value of these three types of scientific research and finding them insufficient to support Dr. Done's testimony, the Court determined that "[s]tudies of this kind, singly or in combination, are not capable of proving causation in human beings in the face of the overwhelming body of contradictory epidemiological evidence." *Id.*

The Court of Appeals then turned to an assessment of the epidemiological studies presented at trial. The defendant relied entirely upon these types of studies; all of which concluded that there was no statistically significant correlation between the use of Bendectin and the incidence of birth defects. Dr. Done conceded that no published work has found this causal link, but relying upon his own recalculations of the epidemiological data available, Dr. Done concluded that there was a statistically relevant correlation. The court expressed skepticism about the value of Dr. Done's recalculations, noting that they were never published nor submitted for peer review while those offered by defendant had been distributed and discussed in the scientific community.

Having thus rejected all of the scientific testimony offered to support the expert testimony of Dr. Done, the Court found that, as a matter of law, the expert testimony presented by plaintiffs at trial could not support a finding of causation. The Court concluded that plaintiffs failed to meet their burden of proof. "[T]he law cannot tolerate a presumption of teratogenicity . . . when [it] becomes an issue in a judicial tribunal." *Id.* at 831. Accordingly, the Court of Appeals affirmed the decision of the District Court and found in favor of defendants.

Plaintiffs maintain that this Court is not bound by the decision in *Richardson* as the doctrine of collateral estoppel does not apply. While plaintiffs correctly argue that the *Richardson* decision does not automatically dispose of the instant action, the precedential value of a decision which is factually similar and is rendered by the Court of Appeals for this jurisdiction, cannot be ignored. *See AFL-CIO v. Marshall,* 617 F.2d 636 (D.C. Cir. 1979); *Department of Energy v. Westland,* 565 F.2d 685 (Cust. & Pat. App. 1977). It is axiomatic that a district court is to follow the law of its own circuit, unless the cases are factually distinguishable.

This Circuit has found, as a matter of law, that expert opinion testimony, which relies upon chemical structure analysis, *in vivo*, *in vitro* studies, or reformulated epidemiological data, is not admissible. Consequently, expert testimony in a Bendectin case cannot be presented to a jury unless it is supported by some other type of scientific evidence. The burden on plaintiffs is to demonstrate that they will provide the jury with expert testimony which relies upon studies other than those disapproved by the Court of Appeals.

Plaintiffs have not met this burden. The majority of the brief submitted by plaintiffs in response to the Order to Show Cause is devoted to an attempt to refute the *Richardson* decision. They attack the conclusion of the Court of Appeals that only the epidemiological studies provided by the defendant are valid as evidence and argue that the *in vivo*, *in vitro*, and restructured epidemiologic studies offered in this case are sufficient to support expert testimony. At least, they maintain, the evidence should be presented to a jury. Plaintiffs refer the Court to cases where this evidence was found to be admissible at trial; however, not one of these cases is controlling.

Given that the evidentiary standards articulated in *Richardson* are controlling here, the majority of plaintiffs' brief is irrelevant. Indeed, nowhere in their papers do the plaintiffs identify any evidence demonstrating causation which would be acceptable under the principles of *Richardson*.

Pursuant to the decision in *Richardson*, it was incumbent upon plaintiffs in this action to demonstrate that they will rely upon scientific evidence other than that which was rejected by the Court of Appeals. Plaintiffs have failed to do so. Instead, they have sought to have this Court decline to follow the decision of the Court of Appeals and find that the scientific evidence proffered by the plaintiffs is reasonable and may be presented to a jury. This the Court refuses to do. The law of this Circuit is that announced in *Richardson*: the issue of causa-

tion shall not be presented to a jury unless the plaintiffs offer scientific evidence other than that which has heretofore been proffered.

CONCLUSION

Accordingly, the Court finds that plaintiffs have failed to meet their burden of proving causation such that the issue may be presented to a trier-of-fact. Judgment in favor of defendant should, therefore, be entered. An Order consistent with this Memorandum Opinion will issue.

DATED: June 30, 1989

/s/ _____
NORMA HOLLOWAY JOHNSON
UNITED STATES DISTRICT JUDGE

United States District Court

FOR THE DISTRICT OF COLUMBIA

ANNE ELISABETH KOLLER,
et al.,
PLAINTIFFS,

vs. Civil No. 80-1258

RICHARDSON-MERRELL, INC.,
DEFENDANT.

Filed June 30, 1989

ORDER AND JUDGMENT

Upon consideration of the record in this case, the memoranda of the parties, and the accompanying Memorandum Opinion, it is this 30th day of June, 1989,

ORDERED that judgment be, and hereby is, entered in favor of defendant; and it is further

ORDERED that the complaint herein be, and hereby is, dismissed.

/s/ _____
NORMA HOLLOWAY JOHNSON
UNITED STATES DISTRICT JUDGE

APPENDIX C

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 89-7167 September Term, 1990

U.S.D.C. Civ. No. 80-1258

Filed Nov. 7 1990

ANN ELISABETH KOLLER,
APPELLANT,

v.

RICHARDSON-MERRELL, INC.

BEFORE: Ruth B. Ginsburg, Buckley and Sentelle,
Circuit Judges

ORDER

Upon consideration of appellant's Petition for Rehearing, filed October 1, 1990, it is

Ordered, by the Court, that the petition is denied.

Per Curiam

FOR THE COURT:
CONSTANCE L. DUPRE, CLERK

BY: /s/ _____
Robert A. Bonner
Deputy Clerk

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 89-7167

September Term, 1990
USDC Civ. No. 80-1258
Filed Nov. 7 1990

ANN ELISABETH KOLLER,
APPELLANT,

v.

RICHARDSON-MERRELL, INC.

BEFORE: Wald, Chief Judge; Mikva, Edwards, Ruth B. Ginsburg, Silberman, Buckley, Williams, D. H. Ginsburg, Sentelle, Thomas, Henderson and Randolph, Circuit Judges

ORDER

Appellant's Suggestion for Rehearing *En Banc* has been circulated to the full Court. No member of the Court requested the taking of a vote thereon. Upon consideration of the foregoing it is

Ordered, by the Court, *en banc*, that the suggestion is denied.

Per Curiam

FOR THE COURT:
CONSTANCE L. DUPRE, CLERK

BY: /s/ _____
Robert A. Bonner
Deputy Clerk

Chief Judge Wald did not participate in this matter.

APPENDIX D

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA

Filed Jan. 25 1983

ANNE ELISABETH KOLLER, *et al.*,
PLAINTIFFS,

v. Civil Action No. 80-1258

RICHARDSON-MERRELL, INC.,
DEFENDANT.

MEMORANDUM OPINION

This matter is before the Court on defendant's motion for summary judgment on the issue of whether Bendectin caused the birth defects of Anne Koller. Defendant contends that plaintiffs' argument that Bendectin is a teratogen that causes limb reductions rests on such speculative evidence and opinions that defendant is entitled to summary judgment. Although defendant does isolate what it considers as weaknesses in plaintiffs' case that may have a significant bearing on whether a directed verdict eventually should be granted, defendants have failed to demonstrate at this point in the proceedings that a genuine issue of material fact does not remain concerning whether Bendectin caused Anne Koller's birth defects. Accordingly, defendant's motion for summary judgment on the issue of causation will be denied.

Defendant makes three arguments to support its contention that plaintiffs' case is nothing more than speculation. First, defendant maintains that plaintiffs are unable to present an

accepted mechanism to explain how Bendectin causes limb reductions. Second, defendant suggests that even though plaintiff may be able to rule out all other known causes of birth defects, Bendectin did not necessarily cause Anne Koller's birth defects because the cause of a majority of all birth defects is unknown. Third, defendant claims that Bendectin did not necessarily cause Anne Koller's birth defects because limb reductions have occurred before Bendectin ever was developed and in countries where Bendectin has never been distributed. While all of defendants' arguments suggest obstacles that plaintiffs will have to confront in presenting their case, none of these arguments is sufficiently compelling to justify the granting of defendant's motion for summary judgment.

Defendant's first argument is that it is entitled to summary judgment because plaintiffs can only speculate on the mechanism by which Bendectin causes limb reductions. Defendant points out that many of plaintiffs' experts have offered no explanation for how Bendectin can act as a teratogen and that those experts of plaintiffs that have suggested three separate theories have relied solely on speculation unconfirmed by any scientific experimentation. It is true that defendant may be able to preclude plaintiffs from presenting any theories to explain Bendectin's teratogenicity if those theories cannot be advanced with any experimental foundation. Yet, the inability to provide any technical explanations for how Bendectin actually causes birth defects does not have a fatal impact on plaintiffs' case. The mechanism by which an allegedly injurious product actually carries out its damage is simply not a prima facie element of plaintiffs' case. For example, while a plaintiff may not be able to explain precisely how a product has triggered a disease such as cancer (a disease whose triggering mechanism has so far eluded the best medical minds), a plaintiff still can prevail if it can be shown by a preponderance of the evidence that the product was responsible for the condition. Of course,

plaintiffs' case may appear weaker if they cannot identify the precise manner in which Bendectin allegedly causes birth defects. Nevertheless, providing the mechanism by which Bendectin allegedly triggers birth defects does not appear to be an essential element of plaintiffs' case.

Defendant's remaining two arguments to support summary judgment are so related in nature that they can be analyzed in a similar manner. Both arguments are founded on the proposition that there are so many unknown factors responsible for birth defects that the fact that Ms. Koller allegedly ingested Bendectin and later gave birth to a child that suffered severe birth defects is insufficient to permit the inference that Bendectin causes these birth defects. Specifically, defendant relies on the conclusions of plaintiffs' experts that the causes of a majority of all birth defects are unknown and that children whose mothers never took Bendectin have suffered limb reductions. In essence, defendant suggests that the natural (unexplained) incidence of birth defects is so high that taking Bendectin during the first trimester is an insufficient basis to infer that Bendectin was responsible for the limb reductions that later occurred. Although defendant's arguments do indicate that attempting to demonstrate that any particular product causes birth defects is a formidable task, it fails to eliminate causation as a genuine issue of material fact at this juncture. The Court cannot conclude that the figures upon which defendant's arguments rest, *e.g.*, multiple limb reductions occurring at a rate of 1-100,000 to 1-1,000,000 live births are anything more than guesstimates that may not be presentable with sufficient certainty to constitute admissible evidence. Moreover, the Court rejects the full implications of defendant's arguments that would effectively deprive any plaintiff of reaching the jury where the product at issue was not an *accepted* cause of birth defects or other diseases. Consequently, the fact that birth defects such as those suffered by Anne Koller have been caused

by unexplained factors (which could have included Bendectin in some instances) does not nullify plaintiffs' contention that Bendectin caused the birth defects of Anne Koller.

What defendant's arguments concerning the significant proportion of birth defects with no explained cause have made clear is that plaintiffs must demonstrate that Bendectin actually caused Anne Koller's birth defects. Defendant has strenuously maintained that there is not a shred of evidence to indicate that there is positive relationship between Bendectin and birth defects. While plaintiffs may have difficulty withstanding a motion for a directed verdict, it appears premature to dismiss plaintiffs' case based on the present record.* Admittedly, defendants have identified some problems with plaintiffs' case. For example, even if the drug experience reports prove admissable, defendants may be entitled to a jury instruction that the drug experience reports alone are insufficient to support a finding that Bendectin causes limb reductions. In addition, it is questionable whether plaintiffs will be able to employ any of the epidemiological or animal studies to prove that Bendectin is a teratogen.** Yet, the complexity of the issue of causation combined with the presence of some uncertainty over what plaintiffs' experts will assert requires that the Court permit plaintiffs at least to present their case to the jury.

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* In virtually all of the cases that defendant cites to support the granting of summary judgment on issue of causation, particularly the swine flu cases, the courts had the benefit of plaintiffs' presentation of their evidence before they found that the plaintiffs had failed to demonstrate causation.

** There is concern whether plaintiffs' experts will be permitted to present any conclusions concerning the epidemiological studies that are not based on an accepted level of statistical significance. Another concern is that plaintiffs have cited a plethora of alleged methodological errors in the epidemiological and animal studies. It is unclear whether any of these alleged errors will be admissable unless plaintiffs can provide a sufficient foundation that the correction of these errors would alter the conclusions of the studies.

An Order consistent with this Memorandum Opinion will be entered this date.

/s/ _____
NORMA HOLLOWAY JOHNSON
UNITED STATES DISTRICT JUDGE

DATE: January 24, 1983

United States District Court

FOR THE DISTRICT OF COLUMBIA

Filed Jan 25, 1983

ANNE ELISABETH KOLLER,
et al.,
PLAINTIFFS,

vs. Civil Action No. 80-1258

RICHARDSON-MERRELL, INC.,
DEFENDANT.

ORDER

Upon consideration of defendant's motion for summary judgment on the issue of causation, plaintiffs' opposition, the accompanying memoranda, and the entire record herein, it is this 24th day of January, 1983,

ORDERED that defendant's motion for summary judgment on the issue of causation be, and hereby is, denied.

/s/ _____
NORMA HOLLOWAY JOHNSON
UNITED STATES DISTRICT JUDGE

APPENDIX E

United States District Court

FOR THE DISTRICT OF COLUMBIA

ANNE ELISABETH KOLLER,
et al.,
PLAINTIFFS,

vs. Civil Action No. 80-1258

RICHARDSON-MERRELL, INC.,
DEFENDANT.

Filed Sep 26 1986

ORDER

Upon consideration of the motion of the plaintiffs for partial summary judgment, defendant's opposition thereto, the parties respective legal memoranda, and the record herein, and it appearing to the Court that there is no basis in law to collaterally estop defendant from litigating the issue of causation in this action, it is this 26th day of September, 1986,

ORDERED that plaintiffs' motion for partial summary judgment be, and hereby is, denied.

/s/ _____
NORMA HOLLOWAY JOHNSON
UNITED STATES DISTRICT JUDGE

APPENDIX F

United States District Court

FOR THE DISTRICT OF COLUMBIA

ANNE ELISABETH KOLLER,
et al.,
PLAINTIFFS,

vs. Civil Action No. 80-1258

RICHARDSON-MERRELL, INC.,
DEFENDANT.

Filed Sep 26 1986

ORDER

Upon consideration of the renewed motion of defendant for summary judgment on the issue of causation, plaintiffs' opposition thereto, the parties' respective legal memoranda, together with the affidavits, exhibits, and the entire record herein, and it appearing to the Court that there exists a genuine issue of material fact as to whether Bendectin caused Anne Koller's birth defects, it is this 26th day of September, 1986,

ORDERED that defendant's renewed motion for summary judgment on the issue of causation be, and hereby is, denied.

/s/ _____
NORMA HOLLOWAY JOHNSON
UNITED STATES DISTRICT JUDGE

(2)

No. 90-1245

FILED
MAR 5 1991
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1990

ANNE ELISABETH KOLLER,
Petitioner,

v.

RICHARDSON-MERRELL INC.,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

---

RESPONDENT'S BRIEF IN OPPOSITION

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QUESTION PRESENTED

Should this Court now grant certiorari to determine the particular quantum of evidence required to sustain a jury verdict that the drug Bendectin causes human birth defects, when the Court has already denied certiorari on that issue three times in the last two Terms and when the Courts of Appeals are unanimous that the body of evidence presented in this case is insufficient to sustain such a verdict?

CORPORATE AFFILIATIONS OF RESPONDENT

Respondent Merrell Dow Pharmaceuticals Inc., sued herein under its predecessor name Richardson-Merrell Inc., is a wholly owned subsidiary of Marion Merrell Dow Inc., which is approximately ⅔ owned by The Dow Chemical Company. Their subsidiaries and affiliates that have securities in the hands of the public are the following:

Arabian Chemical Company Limited;
Compagnie des Services Dowell Schlumberger;
DCU/LB TRUST;
Alamo Land Company Inc.;
Dexco Polymers;
Donichem Chemical KFT;
Transformadora de Etileno S.A.;
Chimtrade;
Vorakim Kimya Sanayi Ve Ticaret A.S.;
Dowell Schlumberger Canada Incorporated;
Fort Saskatchewan Ethylene Storage Limited Partnership;
H-D Tech Inc.;
Wabiskaw Explorations Ltd.;
Cromarty Petroleum Company Limited;
Petroquimica-Dow S.A.;
Ulsan Pacific Chemical Corporation;
Dow Corning Corporation;
Epoxital;
First Chemical Factoring S.p.A.;
Oronzio de Nora Technologies S.p.A.;
Dow Kakoh Kabushiki Kaisha;
Dow Mitsubishi Kasei Limited;
Anticorrosives Industriales Ltda.;
Family Com. e Ind. de Produtos de Limpeza Ltda.;
Dow-United Technologies Composite Products Inc.;
Dowell Schlumberger Corporation;
Dowell Schlumberger Inc.;
El Dorado Terminals Company;

Gurit-Essex, A.G.;
Etoxilados Del Plata S.A.;
Joliet Marine Terminal Trust Estate;
Marion Merrell Dow Inc.;
Gruppo Lepetit S.p.A.;
Merrell Dow Funai K.K.;
MDP (Holdings) Ltd.;
Nordic Laboratories Inc.;
Tanabe-Marion Laboratories;
Fort Saskatchewan Ethylene Storage Corporation;
Pacific Indomas Plastic Indonesia;
Pacific Plastics (Thailand) Limited;
Promix System;
Airco Generon Systems;
DowElanco;
Eurosemances, S.A.;
DowElanco B.V.:
P.T. Pacific Chemicals Indonesia;
Pacific Chemicals Berhad;
Generon Systems;
Generon Systems AG;
Scotdril Offshore Company;
The Cynara Company;
Dow Chemical Iberica S.A.;
Lucky Dow Chemical Ltd.;
SD Group Service Company Ltd.;
Siam Strene Monomer Ltd.;
Siam Synthetic Latex Company;
DH Compounding Company;
Elanco Ihara K.K.;
Zhejiang Pacific Chemical Corporation.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1990

No. 90-1245

ANNE ELISABETH KOLLER,
Petitioner,

v.

RICHARDSON-MERRELL INC.,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

---

RESPONDENT'S BRIEF IN OPPOSITION

INTRODUCTION

This petition represents the fourth time in the last two years that this Court has been asked to grant certiorari to determine the quantum of evidence required to sustain a jury verdict that the drug Bendectin causes human birth defects. The Court denied certiorari on the issue twice in the 1989 Term [1] and a third time in the 1990 Term.[2] This fourth petition repeats almost ver-

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[1] *Richardson* v. *Richardson-Merrell Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989); *Brock* v. *Merrell Dow Pharmaceuticals Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166, *reh'g denied en banc*, 884 F.2d 167 (5th Cir. 1989), *cert. denied*, 110 S. Ct. 1511 (1990).

[2] *Ealy* v. *Richardson-Merrell Inc.*, 897 F.2d 1159 (D.C. Cir.), *cert. denied*, 111 S. Ct. 370 (1990).

batim the same arguments made in the prior three petitions, *i.e.*, that there is a split in the circuit courts on the issue and that the grant of judgment against Bendectin plaintiffs unconstitutionally deprives them of their "day in court."

In fact, however, as was shown in Respondent Merrell Dow's previous oppositions[3] and is shown again here, rather than being split on the matter *all* circuits addressing the question have held that the quantum of evidence presented by Bendectin plaintiffs (and presented again in this case) is insufficient as a matter of law to sustain a jury verdict. And, far from raising a constitutional question, the circuits' decisions represent a routine exercise of the federal courts' responsibility under the Federal Rules of Evidence and Federal Rules of Civil Procedure to avoid duplicative, unnecessary trials where a party's case simply is insufficient to sustain a jury verdict.

At bottom, as was true in the previous three petitions, this case presents nothing more than a *factual* inquiry into the available evidence concerning Bendectin, an inquiry that has produced the circuits' *unanimous* view that that evidence does not reasonably support a determination that Bendectin causes human birth defects. There is nothing in this inquiry that merits this Court's attention. And there is nothing new on this inquiry in the present petition. It should be denied.

COUNTERSTATEMENT OF THE CASE

Petitioner's Statement of the Case is a highly inaccurate account both of the record evidence concerning Bendectin and the courts' analysis of that evidence.[4] Indeed, much of Petitioner's description of Bendectin consists of *completely undocumented* assertions that Bendectin

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[3] Respondent Merrell Dow Pharmaceuticals Inc. ("Merrell Dow") was preceded in interest by Richardson-Merrell Inc.

[4] *See* Pet. 3-17. In this opposition we cite the petition as "Pet." and the separate appendix filed by Petitioner as "Pet. App.".

plaintiffs have made for years, but which the courts have consistently found those plaintiffs unable to establish. Accordingly, in this Counterstatement we describe (a) the documented record concerning Bendectin and (b) the courts' analysis of that record. We follow that with (c) an account of the opinions in this case.

A. The Record Concerning Bendectin

Bendectin is a prescription drug used primarily to treat nausea and vomiting in early pregnancy. Merrell Dow began marketing Bendectin in 1957, shortly after obtaining the approval of the FDA.[5] Thereafter, Bendectin became the leading treatment for women suffering from morning sickness—indeed, between 1957 and 1983 Bendectin was used in over thirty million pregnancies worldwide.[6]

After the thalidomide incident in the early 1960s, questions concerning the teratogenicity[7] of *any* drug or substance ingested during pregnancy arose. Accordingly, in 1963 Merrell Dow began conducting its own studies to determine whether or not Bendectin causes birth defects.[8] Likewise, in the nearly thirty years since then independent researchers throughout the world conducted and published epidemiological studies concerning Bendectin.[9] Significantly, not a single one of those studies concluded that there is a statistically significant association or causal connection between Bendectin and birth defects.[10]

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[5] *See Richardson*, 857 F.2d at 824.

[6] *See id.*

[7] A teratogen is a substance or agent capable of causing abnormal development in humans. *See* T. Stedman, *Stedman's Medical Dictionary* 1563 (25th ed. 1990).

[8] *See Lynch* v. *Merrell-National Laboratories*, 830 F.2d 1190, 1193 (1st Cir. 1987).

[9] *See id.* at 1193-94.

[10] *See id.* at 1194; *Ealy*, 897 F.2d at 1162.

Moreover, in 1980 the FDA's Fertility and Maternal Health Drugs Advisory Committee, after studying the relevant literature and conducting a full hearing on the issue, concluded that "there was no increased incidence of birth defects among Bendectin-exposed infants; that there was no need for further animal or epidemiological studies; and that Bendectin should not be withdrawn from the market." [11] The FDA adopted the Committee's findings, and to this day continues its approval of Bendectin.[12]

Nevertheless, in 1983 Merrell Dow voluntariiy ceased the production and sale of Bendectin as a result of the large costs of litigation concerning the drug.[13] Significantly, after production ceased and notwithstanding Bendectin's prior wide use, there was *no* decrease in the overall incidence of birth defects.[14] Furthermore, even after production ceased, studies of the drug continued to be published concerning its use so that there are to date almost forty published epidemiological studies on the subject.[15] And, most significant of all, from this "wealth of published epidemiological data [that] has been amassed, none * * * has concluded that [Bendectin] is teratogenic." [16] Consequently, there now exists a "nearly uni-

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[11] *Richardson*, 857 F.2d at 827. Petitioner's completely unsupported assertions that the FDA advisory committee was "convened largely at the behest of Merrell [Dow]" and that Merrell Dow thereby "garnered some governmental support" for Bendectin (Pet. 9) are disingenuous in the extreme. There is no evidence whatever in this record or that of any other Bendectin case that even suggests that Merrell Dow exerted any type of improper influence or control over the advisory committee or its conclusions.

[12] *See Richardson*, 857 F.2d at 824.

[13] *See id.*

[14] *See Lynch*, 830 F.2d at 1194.

[15] *Wilson* v. *Merrell Dow Pharmaceuticals Inc.*, 893 F.2d 1149, 1154 (10th Cir. 1990).

[16] *Richardson*, 857 F.2d at 832.

versal scientific consensus" that Bendectin does not cause birth defects.[17]

B. The Unanimous Courts of Appeals' Decisions Concerning Bendectin

In the early 1980s, while the scientific consensus on Bendectin was being formed, judicial dockets throughout the country swelled with Bendectin cases.[18] Most of these cases were resolved in 1985 in a single multidistrict consolidated trial[19] involving more than 1,100 Bendectin plaintiffs.[20] The first—and ultimately dispositive—issue tried and presented to the jury in that case was whether Bendectin in fact causes birth defects.[21] In March 1985 the jury determined that Bendectin does not cause birth defects, and judgment was accordingly entered in Merrell Dow's favor against all plaintiffs who were involved in the consolidated trial.[22] Thereafter, the Sixth Circuit affirmed the jury's verdict,[23] and this Court thereafter denied plaintiffs' petition for certiorari.[24]

Since the multidistrict verdict, unanimous consensus concerning Bendectin has developed in the federal appellate courts, *i.e.*, the courts that have fully addressed the question all have concluded that the current body of scientific evidence is, as a matter of law, an insufficient

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[17] *Id.* at 827.

[18] *See DeLuca* v. *Merrell Dow Pharmaceuticals Inc.*, 911 F.2d 941, 949 (3d Cir. 1990).

[19] *In re Richardson-Merrell Inc. "Bendectin" Prods. Liab. Lit.*, 624 F. Supp. 1212 (S.D. Ohio 1985).

[20] *See In re Bendectin Lit.*, 857 F.2d 290, 294-95 (6th Cir. 1988), *cert. denied*, 488 U.S. 1006 (1989).

[21] *Id.* at 296.

[22] *Id.*

[23] *Id.* at 32[illegible].

[24] 488 U.S. 1006 (1989).

basis upon which a reasonable jury could find that Bendectin causes birth defects.[25] And, as noted, this Court has three times denied certiorari to review those decisions. As a result, there are but a handful of Bendectin cases still pending.[26]

Thus, following the multidistrict verdict, the First Circuit, on appeal of an order entering summary judgment in Merrell Dow's favor, examined the legal sufficiency of the scientific evidence to support a claim that Bendectin causes birth defects.[27] Upon reviewing the records of testimony in other Bendectin trials, the expert depositions and affidavits on file, and the scientific studies since 1963, that court concluded that even when viewing the evidence in the light most favorable to plaintiffs, there was still insufficient evidence upon which plaintiffs could carry their burden of proof.[28]

Thereafter, the District of Columbia Circuit examined the legal sufficiency of the scientific evidence on Bendectin on review of a trial court's decision to enter judgment for Merrell Dow notwithstanding a contrary verdict by the jury.[29] The specific question before the D.C. Circuit in *Richardson* was "not whether there was *some evidence*, but whether * * * there was *sufficient evidence* upon which a jury could properly base a verdict for the [plaintiffs]."[30] In resolving that question, the D.C. Circuit

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[25] *Lynch*, 830 F.2d at 1197; *Richardson*, 857 F.2d at 833; *Brock*, 874 F.2d at 315; *Ealy*, 897 F.2d at 1164; *see also DeLuca*, 911 F.2d at 958 (noting that issue of whether Bendectin is a teratogen may be "susceptible of resolution by summary judgment"); *Wilson*, 893 F.2d at 1155 (affirming verdict in favor of Merrell Dow, and noting that scientific evidence of record was "perhaps even enough to sustain a directed verdict").

[26] *See DeLuca*, 911 F.2d at 943.

[27] *Lynch*, 830 F.2d at 1193-97.

[28] *Id.* at 1193-94, 1197.

[29] *Richardson*, 857 F.2d at 825.

[30] *Id.* at 828 (emphasis in original).

found that based on the wealth of published, peer-reviewed epidemiological data that has been amassed demonstrating that Bendectin does not cause birth defects, the four factors that formed the bases for the contrary opinions of plaintiffs' causation experts—chemical structure activity; *in vitro* studies; *in vivo* animal studies; and unpublished, non-peer-reviewed recalculations of epidemiological studies—failed to provide an adequate foundation to support a conclusion that Bendectin in fact causes birth defects.[31]

The *Richardson* Court based its reasoning on its finding that with respect to Bendectin, the causation issue does not "stand[] at the frontier of current medical and epidemiological inquiry," but is instead "at the other end of the spectrum, a great distance from the 'frontier * * *.'"[32] As a result, "the law now has the benefit of twenty years of scientific study, and the published results must be given their just due."[33] The Court therefore concluded that as a matter of law none of the described types of evidence presented by plaintiffs' experts could provide sufficient evidence upon which a jury could reasonably find that Bendectin causes birth defects.[34] The plaintiffs in *Richardson* thereafter petitioned this Court for a writ of certiorari, but that petition was denied.[35]

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[31] *Id.* at 829-31. Specifically, regarding the first three types of causation evidence—chemical, *in vitro* and *in vivo* studies—the Court stated that "[s]tudies of this kind, singly or in combination, are not capable of proving causation in human beings in the face of an overwhelming body of contradictory epidemiological evidence." *Id.* at 830. The Court found that the fourth kind of evidence—non-peer-reviewed recalculations of published epidemiological studies—is simply insufficient to refute the "wealth of published epidemiological data [that] has been amassed, none of which has concluded" that Bendectin causes birth defects. *Id.* at 831-32.

[32] *Id.* at 832 (citation omitted).

[33] *Id.*

[34] *Id.* at 828, 833.

[35] 110 S. Ct. 218 (1989).

Following *Richardson*, the Fifth Circuit reversed a trial court's entry of judgment on a jury verdict for the plaintiffs in a Bendectin case.[36] In doing so, the Court in *Brock* specifically concluded that the scientific evidence adduced at trial by plaintiffs was insufficient evidence upon which a jury could make a reasonable inference on causation.[37] After the denial of a petition for rehearing and a suggestion for rehearing en banc in *Brock*, this Court denied the plaintiffs' petition for certiorari.[38]

After the Fifth Circuit's decision in *Brock*, the D.C. Circuit again examined the sufficiency of plaintiffs' expert causation testimony in light of "the existing body of published epidemiological studies, all finding no significant statistical association between ingestion of Bendectin and birth defects." [39] In *Ealy*, the Court confirmed "the binding legal precedent" established by the D.C. Circuit in *Richardson*.[40] Finding no material difference in the scientific evidence in the two cases, the Court in *Ealy*, like the Court in *Richardson*, found that the evidence was "so one-sided that no reasonable juror could find on the admissible evidence that Bendectin caused the plaintiff's birth defects." [41] The plaintiffs in *Ealy* also petitioned for certiorari, and that petition as well was denied.[42]

It is against this background, particularly the *Richardson* and *Ealy* decisions, that the Court of Appeals based its summary affirmance of the judgment entered in Merrell Dow's favor in this case.

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[36] *Brock*, 874 F.2d at 315.

[37] *Id.*

[38] 110 S. Ct. 1511 (1990).

[39] *Ealy*, 897 F.2d at 1161, 1164.

[40] *Id.* at 1162.

[41] *Id.* at 1161.

[42] 111 S. Ct. 370 (1990).

C. The Opinions Below

Before trial, the District Court stayed this case pending resolution of the appeal in *Richardson*. Once that appeal was decided, the District Court lifted the stay and issued a show cause order directing plaintiff to "identify specific, admissible, expert evidence of a causal relationship between Bendectin and limb defects which would meet the standards announced in the *Richardson* decision." Pet. App. A4. Thereafter, the District Court reviewed plaintiff's response to the show cause order and found that plaintiff had failed to demonstrate that she would rely on scientific evidence other than that which the D.C. Circuit had rejected as a matter of law in *Richardson*. *Id.* at A8. Consequently, the District Court determined that plaintiff failed to present sufficient evidence upon which a jury could find in her favor on the question of causation. *See id.* at A8-9. The District Court accordingly concluded that Merrell Dow was entitled to judgment as a matter of law.

Plaintiff's appeal of that judgment was stayed pending the decision in *Ealy*. After the *Ealy* Court confirmed the rule of law announced in *Richardson*, the Court of Appeals below—in a *per curiam* Order—summarily affirmed the judgment "substantially for the reasons stated by the district court" in its opinion. *Id.* at A1. Citing *Richardson* and *Ealy*, the Court below noted that summary affirmance was appropriate because the "merits of the parties' positions are so clear." *Id.* at A2.

REASONS FOR DENYING THE WRIT

The entire premise of this petition is the contention that the D.C. Circuit has employed Federal Rule of Evidence 703 in this case as a predicate for claiming broad, far-reaching, unprecedented federal-court powers, in contradiction of other circuit court constructions of Rule 703 and in violation of Petitioner's constitutional rights. None of this is correct. Rather, as we will show, the

judgment in this case is not premised on Rule 703 at all, and the questions raised by Petitioner are simply not presented by this case. Moreover, the judgment entered in this case is of very limited application. Finally, the judgment is in complete accord not only with settled principles established by this Court, but also with all other circuit court decisions addressing similar circumstances. For all these reasons, the writ should be denied.

1. The Questions Raised by Petitioner Are Not Presented by This Case

Petitioner asks the Court to review three questions: (1) whether federal courts may exclude expert testimony under Federal Rule of Evidence 703 on the ground that the testimony is "incorrect and hence not 'reasonable' "; (2) whether federal courts may use the Federal Rules of Evidence to establish "particular conclusions about ultimate scientific facts"; and (3) whether federal courts may constitutionally "pronounce binding conclusions of ultimate scientific fact" that preclude all subsequent parties from challenging those pronouncements. The most important reason for denying the writ is that *none* of these questions is presented by this case because neither of the lower courts held anything remotely resembling the propositions contained in the questions.

In formulating her questions, Petitioner has simply ignored the procedural posture in which the lower courts ruled in this case and the content of their rulings. As noted, the District Court granted summary judgment in Merrell Dow's favor in this case and the Court of Appeals summarily affirmed that judgment. That judgment was issued under Federal Rule of Civil Procedure 56, not Federal Rule of Evidence 703. Indeed, Rule 703 is *not even mentioned* in *either* lower court opinion, much less used as the predicate for the propositions of law framed by Petitioner.

Moreover, far from being based on a binding *unchallengable* pronouncement of scientific fact by the lower

courts, summary judgment was granted on the following unremarkable analysis: in a *prior*, factually similar case (*Richardson*), the evidence adduced was found insufficient as a matter of law to persuade a reasonable jury that Bendectin causes birth defects given the overwhelming evidence adduced to the contrary in that case. In *this* case, the same overwhelming contrary evidence was adduced by Merrell Dow; accordingly, in *this* case Petitioner was expressly invited by a show cause order to present evidence *other* than that found insufficient in *Richardson*. Pet. App. A4. As the District Court stated: "the law of this Circuit is that announced in *Richardson*: the issue of causation shall not be presented to a jury unless the plaintiffs offer scientific evidence other than that which has heretofore been proffered." *Id.* at A8-A9.

Because Petitioner declined or was unable to present any further evidence on the issue, the District Court not surprisingly granted summary judgment, holding that Petitioner had "failed to meet [her] burden of proving causation such that the issue may be presented to a trier of fact." *Id.* at A9. The Court of Appeals thereafter summarily affirmed "substantially for the reasons stated by the District Court * * *." *Id.* at A1.

Thus, the judgment now before this Court is simply not premised on Rule 703 at all, let alone upon the interpretation of that Rule suggested by Petitioner.[43] Rather, it is premised on the standard, obligatory responsibility of the federal courts to ensure that a plaintiff is prepared to adduce evidence sufficient to meet its burden of proof on every element of its claim before permitting a trial. As this Court held in *Celotex Corp.* v. *Catrett*, 477 U.S. 317, 327 (1986), "[t]he Federal Rules of Civil Procedure have for almost 50 years authorized" entry of summary judgment "upon proper showings of the lack of

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[43] We show below that even if the case were deemed to be premised in part on Rule 703, that Rule was correctly applied and the application was not in conflict with the other circuit courts.

a genuine, triable issue * * *." Such entry of judgment is "not * * * a disfavored procedural shortcut," but a means to prevent "factually insufficient claims * * * from going to trial with the attendant unwanted consumption of public and private resources." And such judgment is not merely appropriate, but is "mandate[d]" by the "plain language of Rule 56(c) * * * against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case * * *." *Id.* at 322.

Here, because the evidence Petitioner was prepared to produce was factually insufficient to persuade a reasonable jury on a key element of her case—causation—the District Court directed her to produce further evidence in order to withstand summary judgment. Because Petitioner could produce nothing more, the standard of proof unanimously agreed to by the circuits in *Brock*, *Lynch*, and *Richardson* precluded her from proceeding and avoided the need for a trial.

That outcome is a straightforward application of summary judgment procedure. It is not, as Petitioner would have it, an example of federal courts determining which "scientific truths" are correct and which are not. As this Court held in *Anderson* v. *Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986), at the summary judgment stage the federal courts do not "determine the truth of the matter but * * * whether there is a genuine issue for trial." However, the Court held, there is *no* such "genuine issue" where the party with the burden of proof presents evidence that "is merely colorable" or is "not significantly probative." *Id.* at 249-50. And, where the evidence is "so one-sided" that no reasonable jury could reject it, a case is ripe for decision "as a matter of law." *Id.* at 251-52. *That* is the basis upon which this case was decided.

Petitioner's insistence that something more is involved —that the judgment in this case constitutes an improper,

specialized pronouncement of ultimate scientific fact—is simply not so. Of course, *any* time a court deems evidence insufficient to demonstrate a key fact at issue it has necessarily made a judgment that for burden-of-proof purposes the fact has not been adequately established. But such a determination is not based on a special pronouncement or inappropriate claim of judicial expertise; rather, it is based simply on the failure of the party with the burden of proof to produce enough evidence to persuade a reasonable jury that the asserted fact is so. These simple, basic principles were applied to Bendectin in this case and there is nothing special about their application.[44]

Finally, the proposition that this case presents the specter of the courts unconstitutionally announcing scientific truth by fiat and improperly barring later parties from ever challenging that "truth" is pure fantasy. Again, the only thing the courts in this case determined, based on settled summary judgment procedures and fundamental principles of *stare decisis*, was that a certain quantum of evidence had been found insufficient as a matter of law to raise a "genuine issue" on causation in a tort case. Accordingly, Petitioner was given full and fair opportunity to demonstrate whether she could adduce evidence to exceed the level found insufficient to meet the burden of proof under the governing standard. Because she could not do so, summary judgment was of course entered against her—not because of any unconstitutional treatment of Petitioner, and certainly not because she

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[44] Obviously, these principles do not give way in the face of expert testimony; federal judges must still ensure that such testimony is sufficient to sustain a reasonable jury's verdict. *See, e.g., Matsushita Elec. Indus. Co.* v. *Zenth Radio Corp.*, 475 U.S. 574, 585-87, 593 (1986) (even in case involving highly complex antitrust economic analysis, party still must show "genuine" issue of fact to survive summary judgment, and where "factual context renders [a party's] claim implausible," summary judgment should be granted).

was denied her "day in court," but through a routine application of standard principles.[45]

In the final analysis, the only thing remarkable about this petition is the rule of law Petitioner would have this Court consider. Her view apparently is that there can be *no* standards governing the quantum of evidence in cases involving experts; rather, every plaintiff must be permitted to go to trial with any claim that any expert will support, no matter how many times that precise claim has previously been tried and found wanting, and no matter how many courts have found the claim so unreasonable that no jury could sustain it. Petitioner's view of course has no support whatever in the law and certainly does not merit the attention of this Court on certiorari.

In summary, despite Petitioner's efforts to create issues of importance warranting the Court's review, the questions she frames are simply not presented by this case. Ultimately, this case concerns only a factual inquiry about Bendectin's use and effects. Such an inquiry is not the role of this Court. "We do not grant certiorari to review evidence and to discuss specific facts." *United States* v. *Johnston*, 268 U.S. 220, 227 (1925). Certiorari should be denied.

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[45] Moreover, the circuit courts have certainly not foreclosed later Bendectin plaintiffs from adducing new evidence on the causation issue. To the contrary, as the D.C. Circuit—and others—have recognized, it is only the *current* state of scientific proof that will prove fatal to plaintiffs' cases. "It may well be that future scientific research will generate new * * * data providing an adequate basis for an expert's opinion that Bendectin is a human teratogen * * * Until that day, the existing body of epidemiological studies * * * must be recognized as the measuring stick for the admissibility of expert testimony on this issue." *Ealy*, 897 F.2d at 1163-64; *see also Brock*, 874 F.2d at 315 ("* * * we do not wish this case to stand as a bar to future Bendectin cases in the event that new and conclusive studies emerge which would give a jury a firmer basis on which to determine the issue of causation").

2. The Judgment in This Case Is of Very Limited Application

Although Petitioner asserts that the judgment in this case has far-reaching application, by the clear terms of the summary lower-court opinions the judgment is narrow and is applicable only to cases involving Bendectin. Furthermore, in light of the unanimity of the circuit courts regarding the sufficiency standard applicable to Bendectin cases and this Court's three denials of certiorari to review that standard, the vast bulk of the Bendectin cases are now final. Accordingly, a grant of certiorari in this case would affect very few cases.

Petitioner's arguments to the contrary again ignore what the Court of Appeals below actually did—apply its assessment of the causation evidence affecting Bendectin, as previously announced by that Court in *Richardson* and confirmed in *Ealy*, to the nearly identical evidence offered on that same issue in this case. In fact, because of the precedential force of *Richardson* and *Ealy*, there is no substantive Court of Appeals opinion for this Court to review on certiorari at all, but only a summary affirmance of the District Court's judgment. For this reason, Petitioner's argument is really not an attack on any reasoning of the Court of Appeals in this case, but yet another attack on the reasoning of the D.C. Circuit's earlier decisions in *Richardson* and *Ealy*, which this Court has already declined to review.

Moreover, even if the Court were willing to revisit *Richardson* and *Ealy* in this case, those decisions are themselves quite narrow. As the D.C. Circuit explicitly recognized in *Richardson*, Bendectin presents a "unique" situation in tort litigation, one in which "a wealth of published epidemiological data has been amassed [over twenty years]," and "*none* of [it] has concluded that the drug is teratogenic." 857 F.2d at 832 (emphasis sup-

plied). In those "unique" circumstances, the Court held, the causation question is not at the "frontier of current medical and epidemiological inquiry" where the status of scientific knowledge could reasonably lead experts and juries to different conclusions. *Id.* (citing *Ferebee* v. *Chevron Chemical Co.*, 736 F.2d 1529, 1534 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984)). Rather, the Bendectin inquiry is "at the other end of the spectrum," —where "the body of *published* epidemiological opinions on the subject is extensive, indeed massive, and all such opinions point to the same conclusion." *Richardson*, 857 F.2d at 832; *Ealy*, 897 F.2d at 1162 (emphasis in original). Where that is so—and *only* where that is so—the D.C. Circuit has concluded, as have the other circuits,[46] that reasonable juries could not reject such overwhelming evidence. There is absolutely nothing in any of the circuit courts' opinions suggesting that their treatment of Bendectin would authorize entry of judgment in cases where reasonable juries *could* differ.[47]

Furthermore, not only is the judgment in this case a narrow one—indeed, a "unique" one—the number of cases to which it could yet be applied is quite small. Indeed, as previously discussed, in the wake of the unanimous federal circuit decisions and this Court's three denials of certiorari, only a few Bendectin cases remain pending. Accordingly, any grant of certiorari to review the lower courts' treatment of the "unique" circumstances surrounding Bendectin would have severely limited application.

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[46] *Lynch*, 830 F.2d at 1196-97; *Brock*, 874 F.2d at 315.

[47] *See, e.g., Christophersen* v. *Allied-Signal Corp.*, 902 F.2d 362, 367 (refusing to extend *Brock* to non-Bendectin cases), *reh'g granted en banc*, 914 F.2d 66 (5th Cir. 1990).

3. This Case Presents No Circuit Conflict Meriting This Court's Attention

Petitioner insists, nevertheless, that this case should be seen as presenting a "persistent and important conflict" in the circuit courts "over the construction of Rule 703." Pet. 3, 24, 25. But that is not so. Indeed, as already shown, this case does not present a conflict with respect to Rule 703 at all. Moreover, as also shown, even if this case were thought to rest in part on a D.C. Circuit interpretation of Rule 703, a review of that interpretation by this Court would affect very few cases. Indeed, it is highly unlikely that it would even affect the ultimate judgment in this very case; for even if Petitioner's expert testimony were deemed admissible under Rule 703, the lower court (following *Richardson* and *Ealy*) would still deem that evidence insufficient to support a jury verdict under Federal Rule of Civil Procedure 56. Accordingly, the judgment against Petitioner would in any case be affirmed.

Finally, and in any event, although Petitioner advances much conclusory language about a "clear, persistent and important" conflict in the circuit courts, she never shows that one actually exists. In fact, no significant difference of any kind exists among the circuit courts as to the role of federal courts in determining the admissibility of expert testimony. Rather, each circuit that Petitioner claims to be in conflict over the meaning of Rule 703 has ruled that federal trial courts are obliged, when ruling on a dispute about the admissibility of expert testimony, to conduct a case-by-case, factual inquiry into the sufficiency and foundation of that expert's testimony.[48] And each circuit court of appeals decision cited

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[48] Although there may be minor differences in the precise formulation these courts apply in conducting their review of proffered expert testimony, Petitioner does not and cannot show any of these differences to be improper or to be sufficiently important to warrant this Court's review.

by Petitioner agrees that the question of the admissibility of an expert's testimony is a question of law to be decided by the trial court [49] based on the application and interplay of the several pertinent rules of evidence.[50]

This agreement among the circuit courts [51] includes the decision on which Petitioner most heavily relies, *DeLuca v. Merrell Dow Pharmaceuticals Inc.*, *supra*. Indeed, the Third Circuit in *DeLuca* and the D.C. Circuit in *Richardson* and *Ealy* agree that the admissibility of expert testimony is to be determined by the *court*, and that the *court* must make that determination after conducting a factual

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[49] *See, e.g., Richardson*, 857 F.2d at 833; *Lynch* v. *Merrell-National Laboratories*, 646 F. Supp. 856, 865-66 (D. Mass. 1986), *aff'd*, 830 F.2d 1190 (1st Cir. 1987); *Washington* v. *Armstrong World Industries, Inc.*, 839 F.2d 1121, 1123 (5th Cir. 1988); *Peteet* v. *Dow Chemical Co.*, 868 F.2d 1428, 1432 (5th Cir.), *cert. denied*, 110 S. Ct. 328 (1989); *Wilson*, 893 F.2d at 1153.

[50] Among those rules are Rule 702 (authorizing admission of expert testimony where it will "assist the trier of fact"), Rule 703 (permitting expert testimony if it is reliable and has an adequate foundation), Rule 402 (permitting admission of evidence if it is relevant), and Rule 403 (permitting exclusion of relevant evidence if it can mislead or confuse the fact-finder).

[51] *See, e.g., Richardson*, 857 F.2d at 829 and n.39 (while Rule "703 lays the foundation for our consideration of what constitutes adequate expert testimony," other relevant rules are "702, which permits admission of expert testimony only if it will assist the trier of fact, and * * * 403, which allows the trial court to exclude testimony if it is misleading or confusing, or if its probative value is outweighed by considerations of prejudice, confusion, or waste of time"); *Shatkin* v. *McDonnell Douglas Corp.*, 727 F.2d 202, 208 (2d Cir. 1984) (recognizing the interplay of Rules 403 and 702); *Viterbo* v. *Dow Chemical Co.*, 826 F.2d 420, 422 (5th Cir. 1987) (noting that evidence admissible under Rule 703 must also satisfy Rule 403, which excludes evidence if its probative value is outweighed by other factors). Even the case upon which Petitioner relies for the "proper" construction of Rule 703—*DeLuca*—recognizes that the Rules are to be construed together. 911 F.2d at 952-57 (recognizing the interplay in admissibility decisions of Rules 403, 702 and 703).

inquiry into the foundation and reliability of the testimony. *Richardson*, 857 F.2d at 829; *Ealy*, 897 F.2d at 1161-62; *DeLuca*, 911 F.2d at 952, 958. In fact, the *DeLuca* Court remanded that case so that the lower court could conduct its own "record-supported, factual finding" as required by Rule 703 and the other applicable Rules of Evidence. *DeLuca*, 911 F.2d at 953.

The *DeLuca* Court furthermore expressly acknowledged that, following that case-specific inquiry, the Bendectin issue could be resolved on remand by summary judgment. 911 F.2d at 958. Accordingly, although *DeLuca* remains nonfinal at this point, the possibility remains that the Third Circuit could yet join the other circuits (the First, the Fifth, and the D.C. Circuits) in holding the available Bendectin evidence insufficient as a matter of law to prove causation. There is therefore no existing conflict on either the requirements of Rule 703 or the issue of causation in a Bendectin case meriting this Court's attention on certiorari.

CONCLUSION

For all the foregoing reasons, the petition should be denied.

Respectfully submitted,

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No. 90-1245

IN THE

Supreme Court of the United States

OCTOBER TERM, 1990

ANNE ELISABETH KOLLER,

Petitioner,

v.

RICHARDSON-MERRELL, INC.,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

PETITIONER'S REPLY TO BRIEF IN OPPOSITION

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March 14, 1991

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PETITIONER'S REPLY TO BRIEF IN OPPOSITION

Nothing in the dense smokescreen of misdirection laid down by Merrell's Opposition can obscure the need for this Court to grant certiorari to address statutory and constitutional issues that are vital to much federal litigation, particularly "mass tort" litigation. The construction of the Federal Rules of Evidence relied on by the Court of Appeals below is nowhere defended by Merrell. As the Petition laid out without rebuttal, the Third Circuit has specifically rejected the legal theories of the Court of Appeals below, *on all three Questions Presented*, in its recent decision in *DeLuca* v. *Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 949-54 (3d Cir. 1990). *See* Pet. 17-18, 23-24, 30. The case for certiorari is overwhelming.

1. The importance of the issues presented.

Merrell suggests that review of the D.C. Circuit's interpretation of Rule 703 "would affect very few cases" and that "no significant difference of any kind exists among the circuit courts as to the role of federal courts in determining the admissibility of expert testimony." Opp. 17. This sweeping statement is not supported and is plainly incorrect.

The Petition, at 22-25, explains in detail that several circuits adhere squarely to the plain language and purpose of Rule 703. They hold that Rule 703 is satisfied as long as the type of information used by an expert witness is customarily relied upon by experts to reach conclusions in that field, and that the *weight* of the ultimate conclusions is irrelevant. In doing so they follow the Third Circuit's landmark opinion in *In re Japanese Electronic Products Antitrust Litigation*, 723 F.2d 238 (3d Cir. 1983), *rev'd on other grounds sub nom. Matsushita Elec. Indus. Co.* v. *Zenith Radio Corp.*, 475 U.S. 574 (1986). Other circuits, including the D.C. Circuit below, have

seized on Rule 703 as a tool to permit judges to displace the work of juries in weighing the relative credibility and persuasiveness of expert opinion testimony.

Merrell's somewhat curious response is that all of the cases cited by the Petition agree "that the question of the admissibility of an expert's testimony is a question of law to be decided by the trial court based on the application and interplay of the several pertinent rules of evidence." Opp. 18. But the Petition does not challenge this underlying framework. The Questions Presented arise *within* this framework and address whether the decision below rests on the correct construction of the Federal Rules of Evidence and, if so, whether that construction is constitutional. Merrell's recitation of the "agreement among the circuit courts" over *the framework itself*, Opp. 17-19, is thus irrelevant. The conflict over the core meaning of Rule 703 — a provision enacted by Congress to be uniform throughout the nation — is sharp and significant.

Merrell nowhere denies that this case lies at the center of a fierce battle currently being waged in the lower federal courts over whether it is statutorily and constitutionally permissible for federal judges to employ Congress's Federal Rules of Evidence to screen out expert testimony that may appear to them to have little weight, particularly in "mass tort" cases. Pet. 3-5, 27-30. Shortly after the Petition was filed, the importance of this battle — as well as the extent of the circuit conflict specifically over Rule 703 — was further illustrated in a petition for certiorari filed by a phalanx of defendants in a "mass tort" case involving harms from chemicals knowns as "PCBs". The petition in *General Electric Co.* v. *Knight*, No. 90-1309 (filed Feb. 20, 1991), focuses "on what Judge Patrick E. Higginbotham just a year ago called 'one of the more vexing problems currently facing the federal courts — the role of experts.'" *Id.* at 9 (quoting *Brock* v. *Merrell Dow Pharmaceuticals, Inc.*, 884 F.2d 167, 168 (5th Cir. 1989) (dissent from denial of rehearing *en banc*), *cert. denied*, 110 S. Ct. 1511 (1990)).

That petition attempts to vindicate a district judge who held causation evidence inadmissible under Rule 703 based on his view of the *weight* of contrary opinions. The judge expressly relied upon decisions at issue here, including the D.C. Circuit's holding in *Richardson* v. *Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989). Faithfully adhering to its view of the plain meaning of Rule 703 — that it is not a tool for judicial "screening" of expert testimony — the Third Circuit reversed.[1] The petition faults the Third Circuit for not "set[ting] some modest limits to the power of a party to put before a jury assertions about causation" and notes that today "other Circuits are urging tighter judicial control of opinion testimony." *General Electric* Pet. 9, 11. The petition observes that "'expert' opinions now have taken center stage in much litigation in the federal courts," *id.* at 12-13, and urges that the conflict concerning the meaning of Rule 703 and related Rules merits review by this Court. *Id.* at 14-18.

Regardless of whether that petition warrants certiorari, it illustrates the importance of Rule 703 in federal litigation, and particularly the continuing dispute over the application of evidence rules in "mass tort" cases. This Court declined to review the Third Circuit's 1983 construction of Rule 703 in the *Japanese*

[1] The district judge, "relying on the reasoning of . . . *Richardson* . . . [found] that the expert opinions based on animal studies are inadmissible," given the defendants' "very convincing evidence on the record that says these studies are irrelevant." *In re Paoli Railroad Yard PCB Litigation*, 706 F. Supp. 358, 368 (E.D. Pa. 1988), *rev'd*, 916 F.2d 829 (3d Cir. 1990). Despite testimony that such studies are routinely relied on in the relevant fields in assessing whether PCBs cause health disorders — regardless of the ultimate opinion — the district judge ventured that "[i]f Rule 703 is to be any limit on the ability of expert witnesses to give their opinions, a court must be permitted to examine the bases of the proffered opinions" and "look behind the experts' statements." *Ibid.* The Third Circuit reversed on the strength of its *Japanese Electronics* decision, reiterating that this mode of analysis is not permitted under Rule 703. 916 F.2d at 853-54.

Electronics case, although it reviewed the other issues presented.[2] Since then, however, a number of circuits have refused to follow *Japanese Electronics* without even acknowledging its analysis of the plain meaning of Rule 703. Instead, these circuits are undermining Congress's basic policy choice to curb federal judicial control over expert testimony and to vest in *juries* the task of resolving the credibility and weight of expert testimony. Pet. 18-22.

It is time for this Court to side with the Third Circuit and reject the extraordinary judicial activism reflected in the policy-based use of Rule 703 by the Court of Appeals below, and other circuits, to exclude expert testimony on a judge's view of the weight of the testimony. It is also time to remind the lower federal courts that Congress has ended the free-wheeling days of common-law evidence rulemaking and that the statutory Rules must be applied as written. Pet. 18, 26-27. The lower federal courts should also be instructed that the Constitution bars judges from using *ad hoc* evidence shortcuts in an attempt to minimize the burden of "mass tort" litigation. Pet. 27-30.

2. Merrell's futile attempt to obscure the central reliance of the holding below on Fed. R. Evid. 703, and to evade the statutory and constitutional issues thus presented.

Merrell's principal argument against a grant of certiorari is that none of the questions is properly presented because the Petition supposedly ignores "the procedural posture in which the lower courts ruled in this case and the content of their rulings." Opp. 10. Merrell stresses that the *judgment* below ultimately "was issued under Federal Rule of Civil Procedure 56, not Federal Rule of Evidence 703," Opp. 10, and claims

[2] *See* Petition for Certiorari in *Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, No. 83-2004 (filed June 7, 1984), Question 3. The grant of certiorari was limited to the other two questions. 471 U.S. 1002 (1985).

that the judgment "is simply not premised on Rule 703 at all." Opp. 11. The judgment below is supposedly "a straightforward application of summary judgment procedure," on a finding that Petitioner's evidence "was factually insufficient to persuade a reasonable jury on a key element of [the] case." Opp. 12. Merrell suggests that the Court of Appeals below held only "that a certain quantum of evidence had been found insufficient as a matter of law to raise a 'genuine issue' on causation," and therefore Merrell concludes that "this case concerns only a factual inquiry about Bendectin's use and effects." Opp. 13, 14.

Merrell is wrong. Merrell cannot evade the core Rule 703 holding on admissibility that is the basis of the judgment. This case concerns *only* the pure legal issue of the proper construction of Rule 703, as well as related statutory and constitutional issues. This Court exercises its certiorari jurisdiction to resolve important issues of federal law where they are properly presented, regardless of the factual background of the particular case, and it should do so here.

The Petition amply documented the procedural posture below and the explicit Rule 703 rulings, with no relevant rebuttal from Merrell. The summary opinions below granting summary judgment were based *solely* on the reasoning of *Richardson* and *Ealy*. Pet. 16-17. In turn, the result in *Richardson* and *Ealy* turned *solely* on Rule 703: all of the plaintiffs' expert opinion causation evidence was ruled *inadmissible* under Rule 703 because of the supposedly overwhelming weight of the other side's expert opinion testimony; only *then* was judgment granted under Rule 56, given the lack of any admissible causation evidence. Pet. 12-15.[3]

[3] The fact that the Court of Appeals below *summarily* affirmed the District Court on the basis of *Richardson* and *Ealy* — rather than reiterating the reasoning in those opinions at length — cannot immunize the ruling from review on Merrell's theory that "this Court has already declined to review" those cases. Opp. 15, and therefore it is somehow "too late" for Anne Elisabeth Koller, in

Only selective quotation and misleading characterization permit Merrell to pretend otherwise. Merrell reports that the *Ealy* court "found that the evidence was 'so one-sided that no reasonable juror could find on the admissible evidence that Bendectin caused the plaintiff's birth defects.'" Opp. 8 (quoting *Ealy*, 897 F.2d at 1161). Yet this was merely the *Ealy* court's hornbook snippet reciting the standard of review for judgment n.o.v. determinations, and no serious issue under the *Celotex* trilogy was involved. The only reason that the evidence was "one-sided" and judgment was entered against the Ealys was that they had *no* admissible evidence given the core adverse Rule 703 holding. *Ealy* stressed, in rejecting a strong *Erie* objection, *see* Pet. 12-13 n.6, 15 n.7, that "this case, like *Richardson*, turns on the *admissibility* of the expert testimony" under Rule 703, and that once all of the Ealys' expert opinion testimony "is deemed *inadmissible*, it is self-evident that the evidence is insufficient to support a verdict for the plaintiffs." 897 F.2d at 1163 (emphasis added). Despite Merrell's attempted obfuscation, the only "quantum of evidence" holding under Fed. R. Civ. P. 56 was thus that *the resulting complete lack of any evidence* could not support a finding of causation — a holding irrelevant to this Petition.

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this Petition, to raise the statutory and constitutional flaws posed by the entering of judgment against *her* for these reasons. If the questions she raises are worthy of review, this Court may of course hear them. Nor is there anything to Merrell's attempt to make something out of its unsupported assertion that this Petition "repeats 'almost verbatim' the same arguments made in" earlier petitions. Opp. 1-2. This Petition in fact frames very different issues than those petitions (as a cursory examination of them reveals), and in any event "[t]he denial of a writ of certiorari imports no expression upon the merits of the case, as the bar has been told many times." *United States* v. *Carver*, 260 U.S. 482, 490 (1923).

As explained in the Petition, the summary action of the Court of Appeals below militates in favor of a grant of certiorari, because it reveals that the decision rests on a common-law evidence rulemaking technique that is incompatible with the Federal Rules of Evidence, Pet. 26-27, and because it raises grave constitutional issues, Pet. 27-30. Both sets of issues are important in a range of other cases.

Other federal courts discussing *Richardson* and *Ealy* have had no trouble recognizing that this line of cases employs solely Rule 703 to resolve cases by *excluding* all the evidence, rather than making any judgment about the "legal sufficiency" of the evidence offered but *not* admitted.[4] The Questions Presented are properly before this Court.

3. Merrell's irrelevant and unfounded argument that a circuit court consensus exists that no reasonable jury may find that Bendectin causes birth defects.

Merrell recounts at length its view that there is overwhelming evidence that Bendectin does not cause birth defects, and it argues that a "unanimous consensus" exists among the circuits that no reasonable jury could find for any plaintiff on causation. Opp. 3-8. On this basis, Merrell suggests that this case presents only unique and narrow issues about particular kinds of Bendectin evidence, and therefore that a grant of certiorari "would have severely limited application." Opp. 15-16.

First and foremost, this argument is irrelevant and misperceives the function of this Court. The meaning of a central provision governing the admission of expert opinion testimony — Rule 703 — is what drives this case and warrants review

[4] *E.g. DeLuca, supra*, 911 F.2d at 954 (squarely rejecting the construction of Rule 703 in *Richardson*); *Brock* v. *Merrell Dow Pharmaceuticals, Inc.*, 884 F.2d 167, 168 (5th Cir. 1989) (dissent of Reavley, C.J., and five other judges from denial of rehearing *en banc*), *cert. denied*, 110 S. Ct. 1511 (1990) (noting that unlike the *Richardson* decision, "our panel does not purport to hold that the foundation for the opinions of these experts fails to satisfy Federal Rule of Evidence 703"); *Longmore* v. *Merrell Dow Pharmaceuticals, Inc.*, 737 F. Supp. 1117, 1118, 1120 (D. Idaho 1990) (noting that *Richardson* "held that testimony of the plaintiffs' experts concerning three types of scientific studies was inadmissible under Federal Rule of Evidence 703" and rejecting this view that Rule 703 permits defendants to employ supposedly "overwhelming" statistical data in order "to bulldoze aside the plaintiffs' experts"). Not surprisingly, *Richardson* and *Ealy* are prominently cited in the *General Electric* petition, at 16-18, as key Rule 703 decisions.

by this Court. This is no more a "Bendectin case" than *Hickman* v. *Taylor*, 329 U.S. 495 (1947), was a "tugboat case," *Erie R. Co.* v. *Tompkins*, 304 U.S. 64 (1938), a "railroad case," or *I.N.S.* v. *Chadha*, 462 U.S. 919 (1983), an "immigration case."

As the Petition noted, given the general nature of the Questions Presented and their applicability to *all* litigation involving expert testimony, "the specific content of the scientific testimony in this case" is not at issue. Pet. 5. As noted above, this case does not concern issues of the "legal sufficiency" of this evidence, *once admitted*, to support a jury verdict on causation. Petitioner complains that the courts below improperly considered the relative *weight* of competing expert opinions in passing on the Rule 703 issue, and urges adoption of the Third Circuit's *Japanese Electronics* holding that the weight of opinions is irrelevant under Rule 703.

If this Court grants review to settle the *purely legal issue* of the meaning of Rule 703, and related legal issues, there will be no need to review the content of the specific testimony offered on Bendectin. That evidence will come into play, if petitioner prevails, only on remand, when the District Court decides the admissibility of petitioner's expert testimony under the proper Rule 703 standard. Because the types of data relied on by petitioner's experts are routinely relied on by teratologists in rendering opinions — pro or con — on causation issues, Pet. 5-9, presumably the expert testimony will be admitted. And, as noted below, it is quite probable that petitioner's evidence, once admitted, will survive any renewed challenge to legal sufficiency. Certiorari is therefore proper because petitioner has a clear stake in the proper construction of Rule 703, and in the related issues raised by this case.

Merrell urges denial of review on the assertion that "it is highly unlikely that it would even affect the *ultimate judgment* in this very case," speculating that "even if Petitioner's expert

testimony were deemed admissible under rule 703," the District Court on remand will nevertheless find the evidence legally insufficient to sustain a jury verdict under Fed. R. Civ. P. 56. Opp. 17 (emphasis added). But this Court does not concern itself with the ultimate fate of the cases it selects; it grants review of the questions presented by the cases. This case happens to be an ideal vehicle for examination of important, purely legal issues, *whatever* the ultimate judgment, and certiorari should be granted for that reason.

Second, in any event Merrell's "consensus" argument is unfounded. There is in fact every reason to expect that, upon admission of petitioner's expert testimony on remand, petitioner's evidence will be regarded as sufficient to uphold a jury verdict. As Merrell nowhere denies, the District Court below *twice* rejected Merrell's summary judgment argument that no jury issue existed, even after Merrell drew on the *Celotex* trilogy. Pet. 10-11. A trial was averted only because the District Court felt bound by *Richardson* to rule all of petitioner's evidence inadmissible. Pet. 16. Also, as Merrell nowhere denies, a finding of "legal sufficiency" appears mandated given the definitive ruling of the D.C. Court of Appeals that the type of Bendectin evidence proffered by petitioner satisfies the causation standard under the District of Columbia's substantive law — a "legal sufficiency" ruling which both *Richardson* and *Ealy* accorded respect. Pet. 11 n.5, 12-13 n.6, 15 n.7. Finally, Merrell is utterly wrong in claiming that there is a "unanimous consensus" among the circuits that plaintiffs' causation evidence is legally insufficient to support a jury verdict, for only a lone panel in the Fifth Circuit has so ruled.[5]

[5] As Merrell off-handedly recognizes, only in *Brock* v. *Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166, *reh'g denied en banc*, 884 F.2d 167 (5th Cir. 1989), *cert. denied*, 110 S. Ct. 1511 (1990), has an appellate panel "specifically concluded" in favor of Merrell's insufficiency argument. Opp. 8. The extraordinary, legislative-sounding reasoning of that opinion, *see* Pet. 29-30, was vigorously challenged by Judge Patrick E.

Merrell's exclusive reliance, throughout its Opposition, on such irrelevant and unfounded arguments amounts to an admission that certiorari should be granted in this case to resolve important and recurring legal issues involving the Federal Rules of Evidence.

CONCLUSION

For the reasons stated in the Petition and above, a writ of certiorari should be granted.

Respectfully submitted,

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Higginbotham and five other judges in dissent from denial of rehearing *en banc*, and has not been adopted by any other circuit.

Merrell is wrong in intimating that the opinions of the District Court and the Sixth Circuit in the multidistrict consolidated trial lend support to the legal insufficiency thesis. Opp. 5. In fact both courts went out of their way to note that the jury might just as easily have ruled against Merrell. Pet. 10 n.4. Merrell also errs in suggesting that the First Circuit's decision in *Lynch* v. *Merrell-National Laboratories*, 830 F.2d 1190 (1st Cir. 1987), or the D.C. Circuit's decisions in *Richardson* and *Ealy*, support its claim of legal insufficiency. Opp. 6-7. These decisions rely solely on ruling all the evidence *inadmissible* under Rule 703, not on any review of the legal sufficiency of evidence once admitted. Pet. 11-15.

Not surprisingly given the above, federal trial judges routinely refuse to grant summary judgment in Bendectin cases. Cases just last year include *Longmore*, *supra* note 4; *In re Bendectin Products Litigation*, 732 F. Supp. 744, 749 (E.D. Mich. 1990) (decision of Judge Rubin, who presided over the multidistrict litigation cited in Opp. 5, concluding that "the Court is convinced that there are genuine issues of fact which preclude entry of summary judgment"); and *Wilson* v. *Merrell Dow Pharmaceuticals, Inc.*, No. 83-C-710-E, slip op. at 1 (N.D. Okla. March 1, 1990) (finding that "[s]ubstantial scientific evidence exists to support both the conflicting arguments regarding causation").